(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.

(d) To assure safe use of the additive, in addition to the other information required by the act and paragraph (c) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).

(2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

Dated: July 14, 2010.

Tracey H. Forfa,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2010–17565 Filed 7–16–10; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9493]

RIN 1545–BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIIO–9992–IFC]

45 CFR Part 147

RIN 0938–AQ07

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

DATES: *Effective date.* These interim final regulations are effective on September 17, 2010.

Comment date. Comments are due on or before September 17, 2010.

Applicability dates. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. *WARNING:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210–AB44, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: E-OHPSCA2713.EBSA@dol.gov.*
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210–AB44.

Comments received by the Department of Labor will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIIO–9992–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9992–IFC, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9992–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Internal Revenue Service. Comments to the IRS, identified by REG–120391–10, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* CC:PA:LPD:PR (REG–120391–10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–120391–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (*http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.as*) and information on health reform can be found at *http://www.healthreform.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.[1] The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724[2] (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

[1] The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan," as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

[2] Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations in several phases implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. The first phase in this series was the publication of a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second phase was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third phase was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR 34538). The fourth phase was interim final regulations implementing PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections), published in the **Federal Register** on June 28, 2010 (75 FR 37188). These interim final regulations are being published to implement PHS Act section 2713 (relating to coverage for preventive services). PHS Act section 2713 is generally effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations: PHS Act Section 2713, Coverage of Preventive Health Services (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130)

Section 2713 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations require that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing requirements with respect to:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.[3]
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be "in effect" after it has been adopted by the Director of the Centers for Disease Control and Prevention. A recommendation is considered to be for routine use if it appears on the Immunization Schedules of the Centers for Disease Control and Prevention.
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force). The Department of HHS is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that are required to be covered under these interim final regulations can be found at *http://www.HealthCare.gov/center/regulations/prevention.html.* Together, the items and services described in these recommendations and guidelines are referred to in this preamble as "recommended preventive services."

These interim final regulations clarify the cost-sharing requirements when a recommended preventive service is provided during an office visit. First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit. Second, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit. The reference to tracking individual encounter data was included to provide guidance with respect to plans and issuers that use capitation or similar payment arrangements that do not bill individually for items and services.

Examples in these interim final regulations illustrate these provisions. In one example, an individual receives a cholesterol screening test, a recommended preventive service, during a routine office visit. The plan or issuer may impose cost-sharing requirements for the office visit because the recommended preventive service is billed as a separate charge. A second example illustrates that treatment resulting from a preventive screening can be subject to cost-sharing requirements if the treatment is not itself a recommended preventive service. In another example, an individual receives a recommended preventive service that is not billed as a separate charge. In this example, the primary purpose for the office visit is recurring abdominal pain and not the delivery of a recommended preventive service; therefore the plan or issuer may impose cost-sharing requirements for the office visit. In the final example, an individual receives a recommended preventive service that is not billed as a separate charge, and the delivery of that service is the primary purpose of the office visit. Therefore, the plan or issuer may not impose cost-sharing requirements for the office visit.

With respect to a plan or health insurance coverage that has a network of providers, these interim final regulations make clear that a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. Such a plan or issuer may also impose cost-sharing requirements for recommended preventive services delivered by an out-of-network provider.

These interim final regulations provide that if a recommendation or

[3] Under PHS Act section 2713(a)(5), the Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of any law. Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the Task Force prior to those issued in or around November of 2009 (*i.e.,* those issued in 2002) will be considered current until new recommendations in this area are issued by the Task Force or appear in comprehensive guidelines supported by the Health Resources and Services Administration concerning preventive care and screenings for women.

guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived. Thus, under these interim final regulations, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline.

The statute and these interim final regulations clarify that a plan or issuer continues to have the option to cover preventive services in addition to those required to be covered by PHS Act section 2713. For such additional preventive services, a plan or issuer may impose cost-sharing requirements at its discretion. Moreover, a plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)[4] are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in such recommendations or guidelines must be in effect. These interim final regulations provide that such coverage must be provided for plan years (in the individual market, policy years) beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued. Thus, recommendations and guidelines issued prior to September 23, 2009 must be provided for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For the purpose of these interim final regulations, a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS. For recommendations and guidelines adopted after September 23, 2009, information at *http://www.HealthCare.gov/center/regulations/prevention.html* will be updated on an ongoing basis and will include the date on which the recommendation or guideline was accepted or adopted.

Finally, these interim final regulations make clear that a plan or issuer is not required to provide coverage or waive cost-sharing requirements for any item or service that has ceased to be a recommended preventive service.[5] Other requirements of Federal or State law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any such item or service. For example, PHS Act section 2715(d)(4) requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

Recommendations or guidelines in effect as of July 13, 2010 are described in section V later in this preamble. Any change to a recommendation or guideline that has—at any point since September 23, 2009—been included in the recommended preventive services will be noted at *http://www.HealthCare.gov/center/regulations/prevention.html.* As described above, new recommendations and guidelines will also be noted at this site and plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline went into effect. Therefore, by visiting this site once per year, plans or issuers will have straightforward access to all the information necessary to determine any additional items or services that must be covered without cost-sharing requirements, or to determine any items or services that are no longer required to be covered.

The Affordable Care Act gives authority to the Departments to develop guidelines for group health plans and health insurance issuers offering group or individual health insurance coverage to utilize value-based insurance designs as part of their offering of preventive health services. Value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services. These interim final regulations, for example, permit plans and issuers to implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. The Departments are developing additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits. The Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

The requirements to cover recommended preventive services without any cost-sharing requirements do not apply to grandfathered health plans. *See* 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS

[4] Section 2713(b)(1) refers to an interval between "the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline." While the first part of this statement does not mention guidelines under subsection (a)(4), it would make no sense to treat the services covered under (a)(4) any differently than those in (a)(1), (a)(2), and (a)(3). First, the same sentence refers to "the requirement described in subsection (a)," which would include a requirement under (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women rather than infants, children and adolescents; and other preventive services involving women are addressed in (a)(1), so there is no plausible policy rationale for treating them differently. Third, without this clarification, it would be unclear when such services would have to be covered. These interim final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

[5] For example, if a recommendation of the United States Preventive Services Task Force is downgraded from a rating of A or B to a rating of C or D, or if a recommendation or guideline no longer includes a particular item or service.

Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, the preventive health service provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement. These interim final regulations require plans and issuers to provide coverage for preventive services listed in certain recommendations and guidelines without imposing any cost-sharing requirements. Preparations presumably would have to be made to identify these preventive services. With respect to the changes that would be required to be made under these interim final regulations, group health plans and health insurance issuers subject to these provisions have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact

Under Executive Order 12866 (58 FR 51735), a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of $100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs, benefits, and transfers associated with these interim final regulations, summarized in the following table.

TABLE 1—ACCOUNTING TABLE (2011–2013)

Benefits:
Qualitative: By expanding coverage and eliminating cost sharing for the recommended preventive services, the Departments expect access and utilization of these services to increase. To the extent that individuals increase their use of these services the Departments anticipate several benefits: (1) prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased productivity and fewer sick days; and (4) savings from lower health care costs. Another benefit of these interim final regulations will be to distribute the cost of preventive services more equitably across the broad insured population.
Costs:
Qualitative: New costs to the health care system result when beneficiaries increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage.
Transfers:

TABLE 1—ACCOUNTING TABLE (2011–2013)—Continued

Qualitative: Transfers will occur to the extent that costs that were previously paid out-of-pocket for certain preventive services will now be covered by group health plans and issuers under these interim final regulations. Risk pooling in the group market will result in sharing expected cost increases across an entire plan or employee group as higher average premiums for all enrollees. However, not all of those covered will utilize preventive services to an equivalent extent. As a result, these interim final regulations create a small transfer from those paying premiums in the group market utilizing less than the average volume of preventive services in their risk pool to those whose utilization is greater than average. To the extent there is risk pooling in the individual market, a similar transfer will occur.

A. The Need for Federal Regulatory Action

As discussed later in this preamble, there is current underutilization of preventive services, which stems from three main factors. First, due to turnover in the health insurance market, health insurance issuers do not currently have incentives to cover preventive services, whose benefits may only be realized in the future when an individual may no longer be enrolled. Second, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to take-up, especially in the face of direct, immediate costs. Third, some of the benefits of preventive services accrue to society as a whole, and thus do not get factored into an individual's decision-making over whether to obtain such services.

These interim final regulations address these market failures through two avenues. First, they require coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers in the group and individual markets, thereby overcoming plans' lack of incentive to invest in these services. Second, they eliminate cost-sharing requirements, thereby removing a barrier that could otherwise lead an individual to not obtain such services, given the long-term and partially external nature of benefits.

These interim final regulations are necessary in order to provide rules that plan sponsors and issuers can use to determine how to provide coverage for certain preventive health care services without the imposition of cost sharing in connection with these services.

B. PHS Act Section 2713, Coverage of Preventive Health Services (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130)

1. Summary

As discussed earlier in this preamble, PHS Act section 2713, as added by the Affordable Care Act, and these interim final regulations require a group health plan and a health insurance issuer offering group or individual health insurance coverage to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to the following preventive health services:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force). While these guidelines will change over time, for the purposes of this impact analysis, the Departments utilized currently available guidelines, which include blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, and counseling related to aspirin use, tobacco cessation, obesity, and other topics.
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved.
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force). The Department of HHS is developing these guidelines and expects to issue them no later than August 1, 2011.

2. Preventive Services

For the purposes of this analysis, the Departments used the relevant recommendations of the Task Force and Advisory Committee and current HRSA guidelines as described in section V later in this preamble. In addition to covering immunizations, these lists include such services as blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, genetic testing for the BRCA gene, adolescent depression screening, lead testing, autism testing, and oral health screening and counseling related to aspirin use, tobacco cessation, and obesity.

3. Estimated Number of Affected Entities

For purposes of the new requirements in the Affordable Care Act that apply to group health plans and health insurance issuers in the group and individual markets, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with less than 100 workers. The Departments estimated that there are approximately 72,000 large and 2.8 million small ERISA-covered group health plans with an estimated 97.0 million participants in large group plans and 40.9 million participants in small group plans.[6] The Departments estimate that there are 126,000 governmental plans with 36.1 million participants in large plans and 2.3 million participants in small plans.[7] The Departments estimate there are 16.7 million individuals under age 65 covered by individual health insurance policies.[8]

As described in the Departments' interim final regulations relating to status as a grandfathered health plan,[9] the Affordable Care Act preserves the ability of individuals to retain coverage under a group health plan or health insurance coverage in which the individual was enrolled on March 23, 2010 (a grandfathered health plan). Group health plans, and group and individual health insurance coverage, that are grandfathered health plans do not have to meet the requirements of these interim final regulations. Therefore, only plans and issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these interim final regulations.

[6] All participant counts and the estimates of individual policies are from the U.S. Department of Labor, EBSA calculations using the March 2008 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

[7] Estimate is from the 2007 Census of Government.

[8] US Census Bureau, Current Population Survey, March 2009.

[9] 75 FR 34538 (June 17, 2010).

Plans can choose to relinquish their grandfather status in order to make certain otherwise permissible changes to their plans.[10] The Affordable Care Act provides plans with the ability to maintain grandfathered status in order to promote stability for consumers while allowing plans and sponsors to make reasonable adjustments to lower costs and encourage the efficient use of services. Based on an analysis of the changes plans have made over the past few years, the Departments expect that more plans will choose to make these changes over time and therefore the number of grandfathered health plans is expected to decrease. Correspondingly, the number of plans and policies affected by these interim final regulations is likely to increase over time. In addition, the number of individuals receiving the benefits of the Affordable Care Act is likely to increase over time. The Departments' mid-range estimate is that 18 percent of large employer plans and 30 percent of small employer plans would relinquish grandfather status in 2011, increasing over time to 45 percent and 66 percent respectively by 2013, although there is substantial uncertainty surrounding these estimates.[11]

Using the mid-range assumptions, the Departments estimate that in 2011, roughly 31 million people will be enrolled in group health plans subject to the prevention provisions in these interim final regulations, growing to approximately 78 million in 2013.[12] The mid-range estimates suggest that approximately 98 million individuals will be enrolled in grandfathered group health plans in 2013, many of which already cover preventive services (see discussion of the extent of preventive services coverage in employer-sponsored plans later in this preamble).

In the individual market, one study estimated that 40 percent to 67 percent of individual policies terminate each year. Because all newly purchased individual policies are not grandfathered, the Departments expect that a large proportion of individual policies will not be grandfathered, covering up to and perhaps exceeding 10 million individuals.[13]

However, not all of the individuals potentially affected by these interim final regulations will directly benefit given the prevalence and variation in insurance coverage today. State laws will affect the number of entities affected by all or some provision of these interim final regulations, since plans, policies, and enrollees in States that already have certain requirements will be affected to different degrees.[14] For instance, 29 States require that health insurance issuers cover most or all recommended immunizations for children.[15] Of these 29 States, 18 States require first-dollar coverage of immunizations so that the insurers pay for immunizations without a deductible and 12 States exempt immunizations from copayments (*e.g.*, $5, $10, or $20 per vaccine) or coinsurance (*e.g.*, 10 percent or 20 percent of charges). State laws also require coverage of certain other preventive health services. Every State except Utah mandates coverage for some type of breast cancer screening for women. Twenty-eight States mandate coverage for some cervical cancer screening and 13 States mandate coverage for osteoporosis screening.[16]

Estimation of the number of entities immediately affected by some or all provisions of these interim final regulations is further complicated by the fact that, although not all States require insurance coverage for certain preventive services, many health plans have already chosen to cover these services. For example, most health plans cover most childhood and some adult immunizations contained in the recommendations from the Advisory Committee. A survey of small, medium and large employers showed that 78 percent to 80 percent of their point of service, preferred provider organization (PPO), and health maintenance organization (HMO) health plans covered childhood immunizations and 57 percent to 66 percent covered influenza vaccines in 2001.[17] All 61 health plans (HMOs and PPOs) responding to a 2005 America's Health Insurance Plans (AHIP) survey covered childhood immunizations[18] in their best-selling products and almost all health plans (60 out of 61) covered diphtheria-tetanus-pertussis vaccines and influenza vaccines for adults.[19] A survey of private and public employer health plans found that 84 percent covered influenza vaccines in 2002–2003.[20]

Similarly, many health plans already cover preventive services today, but there are differences in the coverage of these services in the group and individual markets. According to a 2009 survey of employer health benefits, over 85 percent of employer-sponsored health insurance plans covered preventive services without having to meet a deductible.[21] Coverage of preventive services does vary slightly by employer size, with large employers being more likely to cover such services than small employers.[22] In contrast, coverage of preventive services is less prevalent and varies more significantly in the individual market.[23] For PPOs,

[10] See 75 FR 34538 (June 17, 2010).

[11] See 75 FR 34538 (June 17, 2010) for a detailed description of the derivation of the estimates for the percentages of grandfathered health plans. In brief, the Departments used data from the 2008 and 2009 Kaiser Family Foundations/Health Research and Educational Trust survey of employers to estimate the proportion of plans that made changes in cost-sharing requirements that would have caused them to relinquish grandfather status if those same changes were made in 2011, and then applied a set of assumptions about how employer behavior might change in response to the incentives created by the grandfather regulations to estimate the proportion of plans likely to relinquish grandfather status. The estimates of changes in 2012 and 2013 were calculated by using the 2011 calculations and assuming that an identical percentage of plan sponsors will relinquish grandfather status in each year.

[12] To estimate the number of individuals covered in grandfathered health plans, the Departments extended the analysis described in 75 FR 34538, and estimated a weighted average of the number of employees in grandfathered health plans in the large employer and small employer markets separately, weighting by the number of employees in each employer's plan. Estimates for the large employer and small employer markets were then combined, using the estimates supplied above that there are 133.1 million covered lives in the large group market, and 43.2 million in the small group market.

[13] Adele M. Kirk. The Individual Insurance Market: A Building Block for Health Care Reform? *Health Care Financing Organization Research Synthesis.* May 2008.

[14] Of note, State insurance requirements do not apply to self-insured group health plans, whose participants and beneficiaries make up 57 percent of covered employees (in firms with 3 or more employees) in 2009 according to a major annual survey of employers due to ERISA preemption of State insurance laws. *See e.g.*, Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits 2009 Annual Survey* (2009).

[15] *See e.g.*, American Academy of Pediatrics, *State Legislative Report* (2009).

[16] See Kaiser Family Foundation, www.statehealthfacts.org.

[17] *See e.g.*, Mary Ann Bondi *et. al.*, "Employer Coverage of Clinical Preventive Services in the United States," *American Journal of Health Promotion, 20(3), pp. 214–222 (2006).*

[18] The specific immunizations include: DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Hib (*Haemophilus influenza* type b), Hepatitis B, inactivated polio, influenza, MMR (measles, mumps, and rubella), pneumococcal, and varicella vaccine.

[19] McPhillips-Tangum C., Rehm B., Hilton O. "Immunization practices and policies: A survey of health insurance plans." *AHIP Coverage.* 47(1), 32–7 (2006).

[20] *See e.g.*, Matthew M. Davis *et. al.*, "Benefits Coverage for Adult Vaccines in Employer-Sponsored Health Plans," University of Michigan for the CDC National Immunizations Program (2003).

[21] *See e.g.*, Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits 2009 Annual Survey* (2009) available at *http://ehbs.kff.org/pdf/2009/7936.pdf.*

[22] *See e.g.*, Mary Ann Bondi *et. al.*, "Employer Coverage of Clinical Preventive Services in the United States," American Journal of Health Promotion, 20(3), pp. 214–222 (2006).

[23] *See e.g.*, Matthew M. Davis et. al., "Benefits Coverage for Adult Vaccines in Employer-Sponsored Health Plans," University of Michigan

only 66.2 percent of single policies purchased covered adult physicals, while 94.1 percent covered cancer screenings.[24]

In summary, the number of affected entities depends on several factors, such as whether a health plan retains its grandfather status, the number of new health plans, whether State benefit requirements for preventive services apply, and whether plans or issuers voluntarily offer coverage and/or no cost sharing for recommended preventive services. In addition, participants, beneficiaries, and enrollees in such plans or health insurance coverage will be affected in different ways: Some will newly gain coverage for recommended preventive services, while others will have the cost sharing that they now pay for such services eliminated. As such, there is considerable uncertainty surrounding estimation of the number of entities affected by these interim final regulations.

4. Benefits

The Departments anticipate that four types of benefits will result from these interim final regulations. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs. Fourth, the cost of preventive services will be distributed more equitably.

By expanding coverage and eliminating cost sharing for recommended preventive services, these interim final regulations could be expected to increase access to and utilization of these services, which are not used at optimal levels today. Nationwide, almost 38 percent of adult residents over 50 have never had a colorectal cancer screening (such as a sigmoidoscopy or a colonoscopy)[25] and almost 18 percent of women over age 18 have not been screened for cervical cancer in the past three years.[26] Vaccination rates for childhood vaccines are generally high due to State laws requiring certain vaccinations for children to enter school, but recommended childhood vaccines that are not subject to State laws and adult vaccines have lower vaccination rates (e.g., the meningococcal vaccination rate among teenagers is 42 percent).[27] Studies have shown that improved coverage of preventive services leads to expanded utilization of these services,[28] which would lead to substantial benefits as discussed further below.

In addition, these interim final regulations limit preventive service coverage under this provision to services recommended by the Task Force, Advisory Committee, and HRSA. The preventive services given a grade of A or B by the Task Force have been determined by the Task Force to have at least fair or good[29] evidence that the preventive service improves important health outcomes and that benefits outweigh harms in the judgment of an independent panel of private sector experts in primary care and prevention.[30] Similarly, the mission of the Advisory Committee is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The comprehensive guidelines for infants, children, and adolescents supported by HRSA are developed by multidisciplinary professionals in the relevant fields to provide a framework for improving children's health and reducing morbidity and mortality based on a review of the relevant evidence. The statute and interim final regulations limit the preventive services covered to those recommended by the Task Force, Advisory Committee, and HRSA because the benefits of these preventive services will be higher than others that may be popular but unproven.

Research suggests significant health benefits from a number of the preventive services that would be newly covered with no cost sharing by plans and issuers under the statute and these interim final regulations. A recent article in *JAMA* stated, "By one account, increasing delivery of just five clinical preventive services would avert 100,000 deaths per year."[31] These five services are all items and services recommended by the Task Force, Advisory Committee, and/or the comprehensive guidelines supported by HRSA. The National Council on Prevention Priorities (NCPP) estimated that almost 150,000 lives could potentially be saved by increasing the 2005 rate of utilization to 90 percent for eight of the preventive services recommended by the Task Force or Advisory Committee.[32] Table 2 shows eight of the services and the number of lives potentially saved if utilization of preventive services were to increase to 90 percent.

for the CDC National Immunizations Program (2003).

[24] See Individual Health Insurance 2006–2007: A Comprehensive Survey of Premiums, Availability, and Benefits. Available at *http://www.ahipresearch.org/pdfs/Individual_Market_Survey_December_2007.pdf.*

[25] This differs from the Task Force recommendation that individuals aged 50–75 receive fecal occult blood testing, sigmoidoscopy, or colonoscopy screening for colorectal cancer.

[26] For Behavioral Risk Factor Surveillance System Numbers *see e.g.* Centers for Disease Control and Prevention (CDC). *Behavioral Risk Factor Surveillance System Survey Data.* Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, (2008) at *http://apps.nccd.cdc.gov/BRFSS/page.asp?cat=CC&yr=2008&state=UB#CC.*

[27] See *http://www.cdc.gov/vaccines/stats-surv/imz-coverage.htm#nis* for vaccination rates.

[28] *See e.g.*, Jonathan Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Foundation (Oct. 2006). This paper examines an experiment in which copays randomly vary across several thousand individuals. The author finds that individuals are sensitive to prices for health services—i.e. as copays decline, more services are demanded. *See e.g.,* Sharon Long, "On the Road to Universal Coverage: Impacts of Reform in Massachusetts At One Year," *Health Affairs,* Volume 27, Number 4 (June 2008). The author investigated the case of Massachusetts, where coverage of preventive services became a requirement in 2007, and found that for individuals under 300 percent of the poverty line, doctor visits for preventive care increased by 6.1 percentage points in the year after adoption, even after controlling for observable characteristics. Additionally, the incidence of individuals citing cost as the reason for not receiving preventive screenings declined by 2.8 percentage points from 2006 to 2007. In the Massachusetts case, these preventive care services were not necessarily free; therefore, economists would expect a higher differential under these interim final rules because of the price sensitivity of health care usage.

[29] The Task Force defines good and fair evidence as follows. Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes. Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality or consistency of the individual studies, generalizability to routine practice or indirect nature of the evidence on health outcomes. See *http://www.ahrq.gov/clinic/uspstf/gradespre.htm#drec.*

[30] See *http://www.ahrq.gov/clinic/uspstf/gradespre.htm#drec* for details of the Task Force grading.

[31] Woolf, Steven. A Closer Look at the Economic Argument for Disease Prevention. *JAMA* 2009;301(5):536–538.

[32] See National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits.* Partnership for Prevention, August 2007 at *http://www.prevent.org/content/view/129/72/#citations* accessed on 6/22/2010. Lives saved were estimated using models previously developed to rank clinical preventive services. See Maciosek MV, Edwards NM, Coffield AB, Flottemesch TJ, Nelson WW, Goodman MJ, Rickey DA, Butani AB, Solberg LI. Priorities among effective clinical preventive services: methods. *Am J Prev Med* 2006; 31(1):90–96.

TABLE 2.—LIVES SAVED FROM INCREASING UTILIZATION OF SELECTED PREVENTIVE SERVICES TO 90 PERCENT

Preventive service	Population group	Percent utilizing preventive service in 2005	Lives saved annually if percent utilizing preventive service increased to 90 percent
Regular aspirin use	Men 40+ and women 50+	40	45,000
Smoking cessation advice and help to quit	All adult smokers	28	42,000
Colorectal cancer screening	Adults 50+	48	14,000
Influenza vaccination	Adults 50+	37	12,000
Cervical cancer screening in the past 3 years	Women 18–64	83	620
Cholesterol screening	Men 35+ and women 45+	79	2,450
Breast cancer screening in the past 2 years	Women 40+	67	3,700
Chlamydia screening	Women 16–25	40	30,000

Source: National Commission on Prevention Priorities, 2007.

Since financial barriers are not the only reason for sub-optimal utilization rates, population-wide utilization of preventive services is unlikely to increase to the 90 percent level assumed in Table 2 as a result of these interim final regulations. Current utilization of preventive services among insured populations varies widely, but the Departments expect that utilization will increase among those individuals in plans affected by the regulation because the provisions eliminate cost sharing and require coverage for these services.

These interim final regulations are expected to increase the take-up rate of preventive services and are likely, over time, to lead physicians to increase their use of these services knowing that they will be covered, and covered with zero copayment. In the absence of data on the elasticity of demand for these specific services, it is difficult to know precisely how many more patients will use these services. Evidence from studies comparing the utilization of preventive services such as blood pressure and cholesterol screening between insured and uninsured individuals with relatively high incomes suggests that coverage increases usage rates in a wide range between three and 30 percentage points, even among those likely to be able to afford basic preventive services out-of-pocket.[33] A reasonable assumption is that the average increase in utilization of these services will be modest, perhaps on the order of 5 to 10 percentage points for some of them. For services that are generally covered without cost sharing in the current market, the Departments would expect minimal change in utilization.

Preventive services' benefits have also been evaluated individually. Effective cancer screening, early treatment, and sustained risk reduction could reduce the death rate due to cancer by 29 percent.[34] Improved blood sugar control could reduce the risk for eye disease, kidney disease and nerve disease by 40 percent in people with Type 1 or Type 2 diabetes.[35]

Some recommended preventive services have both individual and public health value. Vaccines have reduced or eliminated serious diseases that, prior to vaccination, routinely caused serious illnesses or deaths. Maintaining high levels of immunization in the general population protects the un-immunized from exposure to the vaccine-preventable disease, so that individuals who cannot receive the vaccine or who do not have a sufficient immune response to the vaccine to protect against the disease are indirectly protected.[36]

A second type of benefit from these interim final regulations is improved workplace productivity and decreased absenteeism for school children. Numerous studies confirm that ill health compromises worker output and that health prevention efforts can improve worker productivity. For example, one study found that 69 million workers reported missing days due to illness and 55 million workers reported a time when they were unable to concentrate at work because of their own illness or a family member's illness.[37] Together, labor time lost due to health reasons represents lost economic output totaling $260 billion per year.[38] Prevention efforts can help prevent these types of losses. Studies have also shown that reduced cost-sharing for medical services results in fewer restricted-activity days at work,[39] and increased access to health insurance coverage improves labor market outcomes by improving worker health.[40] Thus, the expansion of benefits and the elimination of cost sharing for preventive services as provided in these

[33] The Commonwealth Fund. "Insurance Coverage and the Receipt of Preventive Care." 2005. *http://www.commonwealthfund.org/Content/Performance-Snapshots/Financial-and-Structural-Access-to-Care/Insurance-Coverage-and-Receipt-of-Preventive-Care.aspx.*

[34] Curry, Susan J., Byers, Tim, and Hewitt, Maria, eds. 2003. *Fulfilling the Potential of Cancer Prevention and Early Detection.* Washington, DC: National Academies Press.

[35] Centers for Disease Control and Prevention. 2010. Diabetes at a Glance. *See http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2010/diabetes_aag.pdf.*

[36] *See* Modern Infectious Disease Epidemiology by Johan Giesecke 1994, Chapter 18, The Epidemiology of Vaccination.

[37] Health and Productivity Among U.S. Workers, Karen Davis, Ph.D., Sara R. Collins, Ph.D., Michelle M. Doty, Ph.D., Alice Ho, and Alyssa L. Holmgren, The Commonwealth Fund, August 2005 *http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2005/Aug/Health-and-Productivity-Among-U-S-Workers.aspx.*

[38] Ibid.

[39] *See e.g.,* RAND, *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate,* Rand Research Brief, Number 9174 (2006), at *http://www.rand.org/pubs/research_briefs/2006/RAND_RB9174.pdf* and Janet Currie *et al.,* "Has Public Health Insurance for Older Children Reduced Disparities in Access to Care and Health Outcomes?", *Journal of Health Economics,* Volume 27, Issue 6, pages 1567–1581 (Dec. 2008). With early childhood interventions, there appear to be improved health outcomes in later childhood. Analogously, health interventions in early adulthood could have benefits for future productivity.

[40] In a RAND policy brief, the authors cite results from the RAND Health Insurance Experiment in which cost-sharing is found to correspond with workers having fewer restricted-activity days—evidence that free care for certain services may be productivity enhancing. *See e.g.,* RAND, *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate,* Rand Research Brief, Number 9174 (2006), at *http://www.rand.org/pubs/research_briefs/2006/RAND_RB9174.pdf. See e.g.* Janet Currie *et. al.,* "Has Public Health Insurance for Older Children Reduced Disparities in Access to Care and Health Outcomes?" *Journal of Health Economics,* Volume 27, Issue 6, pages 1567–1581 (Dec. 2008). With early childhood interventions, there appears to be improved health outcomes in later childhood. Analogously, health interventions in early adulthood could have benefits for future productivity. Council of Economic Advisers. "The Economic Case for Health Reform." (2009).

interim final regulations can be expected to have substantial productivity benefits in the labor market.

Illnesses also contribute to increased absenteeism among school children, which could be avoided with recommended preventive services. In 2006, 56 percent of students missed between one and five days of school due to illness, 10 percent missed between six and ten days and five percent missed 11 or more days.[41] Obesity in particular contributes to missed school days: One study from the University of Pennsylvania found that overweight children were absent on average 20 percent more than their normal-weight peers.[42] Studies also show that influenza contributes to school absenteeism, and vaccination can reduce missed school days and indirectly improve community health.[43] These interim final regulations will ensure that children have access to preventive services, thus decreasing the number of days missed due to illness.[44] Similarly, regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs. For example, one study of Medicaid enrolled children found that when children were up to date for their age on their schedule of well-child visits, they were less likely to have an avoidable hospitalization at a later time.[45]

A third type of benefit from some preventive services is cost savings. Increasing the provision of preventive services is expected to reduce the incidence or severity of illness, and, as a result, reduce expenditures on treatment of illness. For example, childhood vaccinations have generally been found to reduce such expenditures by more than the cost of the vaccinations themselves and generate considerable benefits to society. Researchers at the Centers for Disease Control and Prevention (CDC) studying the economic impact of DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Td (tetanus and diphtheria toxoids), Hib (*Haemophilus influenza* type b), IPV (inactivated poliovirus), MMR (measles, mumps and rubella), Hepatitis B and varicella routine childhood vaccines found that every dollar spent on immunizations in 2001 was estimated to save $5.30 on direct health care costs and $16.50 on total societal costs of the diseases as they are prevented or reduced (direct health care associated with the diseases averted were $12.1 billion and total societal costs averted were $33.9 billion).[46]

A review of preventive services by the National Committee on Prevention Priorities found that, in addition to childhood immunizations, two of the recommended preventive services—discussing aspirin use with high-risk adults and tobacco use screening and brief intervention—are cost-saving on net.[47] By itself, tobacco use screening with a brief intervention was found to save more than $500 per smoker.[48]

Another area where prevention could achieve savings is obesity prevention and reduction. Obesity is widely recognized as an important driver of higher health care expenditures.[49] The Task Force recommends children over age six and adults be screened for obesity and be offered or referred to counseling to improve weight status or promote weight loss. Increasing obesity screening and referrals to counseling should decrease obesity and its related costs. If providers are able to proactively identify and monitor obesity in child patients, they may reduce the incidence of adult health conditions that can be expensive to treat, such as diabetes, hypertension, and adult obesity.[50] One recent study estimated that a one-percentage-point reduction in obesity among twelve-year-olds would save $260.4 million in total medical expenditures.[51]

A full quantification of the cost savings from the extension of coverage of preventive services in these interim final regulations is not possible, but to illustrate the potential savings, an assessment of savings from obesity reduction was conducted. According to the CDC, in 2008, 34.2 percent of U.S. adults and 16.9 percent of children were obese (defined as having a body mass index (BMI) of 30.0 or greater).[52] Obesity is associated with increased risk for coronary heart disease, hypertension, stroke, type 2 diabetes, several types of cancer, diminished mobility, and social stigmatization.[53] As a result, obesity is widely recognized as an important driver of higher health care expenditures on an individual [54] and national level.[55]

As described below, the Departments' analysis assumes that the utilization of preventive services will increase when they are covered with zero copayment, and these interim final regulations are expected to increase utilization of dietary counseling services both among people who currently have the service covered with a copayment and among people for whom the service is not currently covered at all.

Data from the 2009 Kaiser Family Foundation Employer Health Benefits Survey shows that 73 percent of employees with employer-sponsored insurance from a small (< 200 employees) employer do not currently have coverage for weight loss programs,

[41] Bloom B, Cohen RA. Summary health statistics for U.S. children: National Health Interview Survey, 2006. Vital Health Stat 2007;10(234). Available at *http://www.cdc.gov/nchs/nhis.htm.*

[42] University of Pennsylvania 2007: *http://www.upenn.edu/pennnews/news/childhood-obesity-indicates-greater-risk-school-absenteeism-university-pennsylvania-study-revea.*

[43] Davis, Mollie M., James C. King, Ginny Cummings, and Laurence S. Madger. "Countywide School-Based Influenza Immunization: Direct and Indirect Impact on Student Absenteeism." *Pediatrics* 122.1 (2008).

[44] Moonie, Sheniz, David A. Sterling, Larry Figgs, and Mario Castro. "Asthma Status and Severity Affects Missed School Days." *Journal of School Health* 76.1 (2006): 18–24.

[45] Bye, "Effectiveness of Compliance with Pediatric Preventative Care Guidelines Among Medicaid Beneficiaries."

[46] Fangjun Zhou, Jeanne Santoli, Mark L. Messonnier, Hussain R. Yusuf, Abigail Shefer, Susan Y. Chu, Lance Rodewald, Rafael Harpaz. Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States. *Archives of Pediatric and Adolescent Medicine 2005;* 159(12): 1136–1144. The estimates of the cost savings are based on current immunization levels. The incremental impact of increasing immunization rates is likely to be smaller, but still significant and positive.

[47] Maciosek MV, Coffield AB, Edwards NM, Coffield AB, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: Results of a Systematic Review and Analysis. *Am J Prev Med 2006;* 31(1):52–61.

[48] Solberg LI, Maciosek, MV, Edwards NM, Khanchandani HS, and Goodman MJ. Repeated tobacco-use screening and intevention in clinical practice: Health impact and cost effectiveness. American Journal of Preventive Medicine. 2006;31(1).

[49] Congressional Budget Office. "Technological Change and the Growth of Health Care Spending." January 2008. Box 1, pdf p. 18. *http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf.*

[50] "Working Group Report on Future Research Directions in Childhood Obesity Prevention and Treatment." National Heart, Lung and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services (2007), available at *http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm.*

[51] *Ibid.*

[52] Centers for Disease Control and Prevention. "Obesity and Overweight." 2010. *http://www.cdc.gov/nchs/fastats/overwt.htm.*

[53] Agency for Healthcare Research and Quality (AHRQ). "Screening for Obesity in Adults." December 2003. *http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.pdf.*

[54] Thorpe, Kenneth E. "The Future Costs of Obesity: National and State Estimates of the Impact of Obesity on Direct Health Care Expenses." November 2009; McKinsey Global Institute. "Sample data suggest that obese adults can incur nearly twice the annual health care costs of normal-weight adults." 2007.

[55] Congressional Budget Office. "Technological Change and the Growth of Health Care Spending." January 2008. Box 1, pdf p. 18. *http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf.*

compared to 38 percent at large firms.[56] In the illustrative analysis below, the share of individuals without weight loss coverage in the individual market is assumed to be equal to the share in the small group market.

The size of the increase in the number of individuals receiving dietary counseling or other weight loss services will be limited by current physician practice patterns, in which relatively few individuals who are obese receive physician recommendations for dietary counseling. In one study of patients at an internal medicine clinic in the Bronx, NY, approximately 15 percent of obese patients received a recommendation for dietary counseling.[57] Similarly, among overweight and obese patients enrolled in the Cholesterol Education and Research Trial, approximately 15 to 20 percent were referred to nutrition counseling.[58]

These interim final regulations are expected to increase the take-up rate of counseling among patients who are referred to it, and may, over time, lead physicians to increase their referral to such counseling, knowing that it will be covered, and covered without cost sharing. The effect of these interim final regulations is expected to be magnified because of the many other public and private sector initiatives dedicated to combating the obesity epidemic.

In the absence of data on take-up of counseling among patients who are referred by their physicians, it is difficult to know what fraction of the estimated 15 percent to 20 percent of patients who are currently referred to counseling follow through on that referral, or how that fraction will change after coverage of these services is expanded. A reasonable assumption is that utilization of dietary counseling among patients who are obese might increase by five to 10 percentage points as a result of these interim final regulations. If physicians change their behavior and increase the rate at which they refer to counseling, the effect might be substantially larger.

The share of obese individuals without weight loss coverage is estimated to be 29 percent.[59] It is assumed that obese individuals have health care costs 39 percent above average, based on a McKinsey Global Institute analysis.[60] The Task Force noted that counseling interventions led to sustained weight loss ranging from four percent to eight percent of body weight, although there is substantial heterogeneity in results across interventions, with many interventions having little long-term effect.[61] Assuming midpoint reduction of six percent of body weight, the BMI for an individual taking up such an intervention would fall by six percent as well, as height would remain constant. Based on the aforementioned McKinsey Global Institute analysis, a six percent reduction in BMI for an obese individual (from 32 to around 30, for example) would result in a reduction in health care costs of approximately five percent. This parameter for cost reduction is subject to considerable uncertainty, given the wide range of potential weight loss strategies with varying degrees of impact on BMI, and their interconnectedness with changes in individual health care costs.

Multiplying the percentage reduction in health care costs by the total premiums of obese individuals newly gaining obesity prevention coverage allows for an illustrative calculation of the total dollar reduction in premiums, and dividing by total premiums for the affected population allows for an estimate of the reduction in average premiums across the entire affected population. Doing so results in a potential private premium reduction of 0.05 percent to 0.1 percent from lower health care costs due to a reduction in obesity for enrollees in non-grandfathered plans. This does not account for potential savings in Medicaid, Medicare, or other health programs.

A fourth benefit of these interim final regulations will be to distribute the cost of preventive services more equitably across the broad insured population. Some Americans in plans affected by these regulations currently have no coverage of certain recommended preventive services, and pay for them entirely out-of-pocket. For some individuals who currently have no coverage of certain recommended preventive services, these interim final regulations will result in a large savings in out-of-pocket payments, and only a small increase in premiums. Many other Americans have limited coverage of certain recommended preventive services, with large coinsurance or deductibles, and also make substantial out-of-pocket payments to obtain preventive services. Some with limited coverage of preventive services will also experience large savings as a result of these interim final regulations. Reductions in out-of-pocket costs are expected to be largest among people in age groups in which relatively expensive preventive services are most likely to be recommended.

5. *Costs and Transfers*

The changes in how plans and issuers cover the recommended preventive services resulting from these interim final regulations will result in changes in covered benefits and premiums for individuals in plans and health insurance coverage subject to these interim final regulations. New costs to the health system result when beneficiaries increase their use of preventive services in response to the changes in coverage of preventive services. Cost sharing, including coinsurance, deductibles, and copayments, divides the costs of health services between the insurer and the beneficiaries. The removal of cost sharing increases the quantity of services demanded by lowering the direct cost of the service to consumers. Therefore, the Departments expect that the statute and these interim final regulations will increase utilization of the covered preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand.

Several studies have found that individuals are sensitive to prices for health services.[62] Evidence that consumers change their utilization of preventive services is available from CDC researchers who studied out-of-pocket costs of immunizations for

[56] Kaiser Family Foundation. 2009 Employer Health Benefits Annual Survey. Public Use File provided to CEA; documentation of statistical analysis available upon request. *See http://ehbs.kff.org.*

[57] Davis NJ, Emerenini A, Wylie-Rosett J. "Obesity management: physician practice patterns and patient preference," *Diabetes Education.* 2006 Jul–Aug; 32(4):557–61.

[58] Molly E. Waring, PhD, Mary B. Roberts, MS, Donna R. Parker, ScD and Charles B. Eaton, MD, MS. "Documentation and Management of Overweight and Obesity in Primary Care," *The Journal of the American Board of Family Medicine* 22 (5): 544–552 (2009).

[59] This estimate is constructed using a weighted average obesity rate taking into account the share of the population aged 0 to 19 and 20 to 74 and their respective obesity rates, derived from Census Bureau and Centers for Disease Control and Prevention data. U.S. Census Bureau. "Current Population Survey (CPS) Table Creator." 2010. *http://www.census.gov/hhes/www/cpstc/cps_table_creator.html.* Centers for Disease Control and Prevention. "Obesity and Overweight." 2010. *http://www.cdc.gov/nchs/fastats/overwt.htm.*

[60] McKinsey Global Institute Analysis provided to CEA.

[61] Agency for Healthcare Research and Quality (AHRQ). "Screening for Obesity in Adults." December 2003. p. 4. *http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.pdf.*

[62] *See e.g.,* Jonathan Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond,* Kaiser Family Foundation (Oct. 2006). This paper examines an experiment in which copays randomly vary across several thousand individuals. The author finds that individuals are sensitive to prices for health services—*i.e.,* as copays decline, more services are demanded.

privately insured children up to age 5 in families in Georgia in 2003, to find that a one percent increase in out-of-pocket costs for routine immunizations (DTaP, IPV, MMR, Hib, and Hep B) was associated with a 0.07 percent decrease in utilization.[63]

Along with new costs of induced utilization, there are transfers associated with these interim final regulations. A transfer is a change in who pays for the services, where there is not an actual change in the level of resources used. For example, costs that were previously paid out-of-pocket for certain preventive services will now be covered by plans and issuers under these interim final regulations. Such a transfer of costs could be expected to lead to an increase in premiums.

a. Estimate of Average Changes in Health Insurance Premiums

The Departments assessed the impact of eliminating cost sharing, increases in services covered, and induced utilization on the average insurance premium using a model to evaluate private health insurance plans against a nationally representative population. The model is based on the Medical Expenditure Panel Survey data from 2004, 2005, and 2006 on household spending on health care, which are scaled to levels consistent with the CMS projections of the National Health Expenditure Accounts.[64] This data is combined with data from the Employer Health Benefits Surveys conducted by the Kaiser Family Foundation and Health Research and Education Trust to model a "typical PPO coverage" plan. The model then allows the user to assess changes in covered expenses, benefits, premiums, and induced utilization of services resulting from changes in the characteristics of the plan. The analysis of changes in coverage is based on the average per-person covered expenses and insurance benefits. The average covered expense is the total charge for covered services; insurance benefits are the part of the covered expenses covered by the insurer. The effect on the average premium is then estimated based on the percentage changes in the insurance benefits and the distribution of the individuals across individual and group markets in non-grandfathered plans.

The Departments assume that the percent increase for insurance benefits and premiums will be the same. This is based on two assumptions: (1) That administrative costs included in the premium will increase proportionally with the increase in insurance benefits; and (2) that the increases in insurance benefits will be directly passed on to the consumer in the form of higher premiums. These assumptions bias the estimates of premium changes upward. Using this model, the Departments assessed: (1) Changes in cost-sharing for currently covered and utilized services, (2) changes in services covered, and (3) induced utilization of preventive services. There are several additional sources of uncertainty concerning these estimates. First, there is no accurate, granular data on exactly what baseline coverage is for the particular preventive services addressed in these interim final regulations. Second, there is uncertainty over behavioral assumptions related to additional utilization that results from reduced cost-sharing. Therefore, after providing initial estimates, the Departments provide a sensitivity analysis to capture the potential range of impacts of these interim final regulations.

From the Departments' analysis of the Medical Expenditure Panel Survey (MEPS) data, controlled to be consistent with projections of the National Health Expenditure Accounts, the average person with employer-sponsored insurance (ESI) has $264 in covered expenses for preventive services, of which $240 is paid by insurance, and $24 is paid out-of-pocket.[65] When preventive services are covered with zero copayment, the Departments expect the average preventive benefit (holding utilization constant) will increase by $24. This is a 0.6 percent increase in insurance benefits and premiums for plans that have relinquished their grandfather status. A similar, but larger effect is expected in the individual market because existing evidence suggests that individual health insurance policies generally have less generous benefits for preventive services than group health plans. However, the evidence base for current coverage and cost sharing for preventive services in individual health insurance policies is weaker than for group health plans, making estimation of the increase in average benefits and premiums in the individual market highly uncertain.

For analyses of changes in covered services, the Departments used the Blue Cross/Blue Shield Standard (BC/BS) plan offered through the Federal Employees Health Benefits Program as an average plan.[66] Other analyses have used the BC/BS standard option as an average plan as it was designed to reflect standard practice within employer-sponsored health insurance plans.[67] BC/BS covers most of the preventive services listed in the Task Force and Advisory Committee recommendations, and most of the preventive services listed in the comprehensive guidelines for infants, children, and adolescents supported by HRSA. Not covered by the BC/BS Standard plan are the recommendations for genetic testing for the BRCA gene, adolescent depression screening,[68] lead testing, autism testing, and oral health screening.[69]

The Departments estimated the increase in benefits from newly covered services by estimating the number of new services that would be provided times the cost of providing the services, and then spread these new costs across the total insured population. The Departments estimated that adding coverage for genetic screening and depression screening would increase insurance benefits an estimated 0.10 percent. Adding lead testing, autism testing, and oral health screening would increase insurance benefits by an estimated 0.02 percent. This results in a total average increase in insurance benefits on these services of 0.12 percent, or just over $4 per insured person. This increase represents a mixture of new costs and transfers, dependent on whether beneficiaries previously would have purchased these services on their own. It is also important to remember that actual plan

[63] *See e.g.,* Noelle-Angelique Molinari *et al.,* "Out-of-Pocket Costs of Childhood Immunizations: A Comparison by Type of Insurance Plan," *Pediatrics,* 120(5) pp. 148–156 (2006).

[64] The National Health Expenditure Accounts (NHEA) are the official estimates of total health care spending in the United States. *See http://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp.*

[65] The model does not distinguish between recommended and non-recommended preventive services, and so this likely represents an overestimate of the insurance benefits for preventive services.

[66] The Blue Cross Blue Shield standard option plan documentation is available online at *http://fepblue.org/benefitplans/standard-option/index.html.*

[67] Frey A, Mika S, Nuzum R, and Schoen C. "Setting a National Minimum Standard for Health Benefits: How do State Benefit Mandates Compare with Benefits in Large-Group Plans?" Issue Brief. Commonwealth Fund June 2009 available at *http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2009/Jun/Setting-a-National-Minimum-Standard-for-Health-Benefits.aspx.*

[68] The Task Force recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for BRCA testing and screening of adolescents (12–18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.

[69] Lead, autism, and oral health screening are from the HRSA comprehensive guidelines.

impacts will vary depending on baseline benefit levels, and that grandfathered health plans will not experience any impact from these interim final regulations. The Departments expect the increase to be larger in the individual market because coverage of preventive services in the individual market is less complete than coverage in the group market, but as noted previously, the evidence base for the individual market is weaker than that of the group market, making detailed estimates of the size of this effect difficult and highly uncertain.

Actuaries use an "induction formula" to estimate the behavioral change in response to changes in the relative levels of coverage for health services. For this analysis, the Departments used the model to estimate the induced demand (the increased use of preventive services). The model uses a standard actuarial formula for induction 1/(1+alpha*P), where alpha is the "induction parameter" and P is the average fraction of the cost of services paid by the consumer. The induction parameter for physician services is 0.7, derived by the standard actuarial formula that is generally consistent with the estimates of price elasticity of demand from the RAND Health Insurance Experiment and other economic studies.[70] Removing cost sharing for preventive services lowers the direct cost to consumers of using preventive services, which induces additional utilization, estimated with the model above to increase covered expenses and benefits by approximately $17, or 0.44 percent in insurance benefits in group health plans. The Departments expect a similar but larger effect in the individual market, although these estimates are highly uncertain.

The Departments calculated an estimate of the average impact using the information from the analyses described above, using estimates of the number of individuals in non-grandfathered health plans in the group and individual markets in 2011. The Departments estimate that premiums will increase by approximately 1.5 percent on average for enrollees in non-grandfathered plans. This estimate assumes that any changes in insurance benefits will be directly passed on to the consumer in the form of changes in premiums. As mentioned earlier, this assumption biases the estimates of premium change upward.

[70] Standard formula best described in "Quantity-Price Relationships in Health Insurance", Charles L Trowbridge, Chief Actuary, Social Security Administration (DHEW Publication No. (SSA)73–11507, November 1972).

b. Sensitivity analysis

As discussed previously, there is substantial uncertainty associated with the estimates presented above. To address the uncertainty in the group market, the Departments first varied the estimated change to underlying benefits, to address the particular uncertainty behind the estimate of baseline coverage of preventive services in the group market. The estimate for the per person annual increase in insurance benefits from adding coverage for new services is approximately $4. The Departments considered the impact of a smaller and larger addition in benefits of approximately $2 and $6 per person. To consider the impact of uncertainty around the size of the behavioral change (that is, the utilization of more services when cost sharing is eliminated), the Departments analyzed the impact on insurance benefits if the behavioral change were 15 percent smaller and 15 percent larger.

In the individual market, to accommodate the greater uncertainty relative to the group market, the Departments considered the impact of varying the increase in benefits resulting from cost shifting due to the elimination of cost sharing, in addition to varying the cost of newly covered services and behavioral change.

Combining results in the group and individual markets for enrollees in non-grandfathered plans, the Departments' low-end is a few tenths of a percent lower than the mid-range estimate of approximately 1.5 percent, and the high-end estimate is a few tenths of a percent higher. Grandfathered health plans are not subject to these interim final regulations and therefore would not experience this premium change.

6. Alternatives Considered

Several provisions in these interim final regulations involved policy choices. One was whether to allow a plan or issuer to impose cost sharing for an office visit when a recommended preventive service is provided in that visit. Sometimes a recommended preventive service is billed separately from the office visit; sometimes it is not. The Departments decided that the cost sharing prohibition of these interim final regulations applies to the specific preventive service as recommended by the guidelines. Therefore, if the preventive service is billed separately from the office visit, it is the preventive service that has cost sharing waived, not the entire office visit.

A second policy choice was if the preventive service is not billed separately from the office visit, whether these interim final regulations should prohibit cost sharing for any office visit in which any recommended preventive service was administered, or whether cost sharing should be prohibited only when the preventive service is the primary purpose of the office visit. Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application of these interim final regulations; for example, a person who sees a specialist for a particular condition could end up with a zero copayment simply because his or her blood pressure was taken as part of the office visit. This could create financial incentives for consumers to request preventive services at office visits that are intended for other purposes in order to avoid copayments and deductibles. The increased prevalence of the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services.

A third issue involves health plans that have differential cost sharing for services provided by providers who are in and out of their networks. These interim final regulations provide that a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer may also impose cost sharing for recommended preventive services delivered by an out-of-network provider. The Departments considered that requiring coverage by out-of-network providers at no cost sharing would result in higher premiums for these interim final regulations. Plans and issuers negotiate allowed charges with in-network providers as a way to promote effective, efficient health care, and allowing differences in cost sharing in- and out-of-network enables plans to encourage use of in-network providers. Allowing zero cost sharing for out of network providers could reduce providers' incentives to participate in insurer networks. The Departments decided that permitting cost sharing for recommended preventive services provided by out-of-network providers is the appropriate option to preserve choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.

C. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes

certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B or title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

Moreover, under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of the Affordable Care Act and minimize the impact on small entities.

D. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

E. Paperwork Reduction Act: Department of Labor, Department of the Treasury, and Department of Health and Human Services

These interim final regulations are not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) because it does not contain a "collection of information" as defined in 44 U.S.C. 3502 (11).

F. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of $100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, these interim final regulations have been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

H. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these interim final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of the Affordable Care Act) are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the "narrowest" preemption of State laws. (*See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.) States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to "prevent the application of" the Affordable Care Act, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit

the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these interim final regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached regulations in a meaningful and timely manner.

V. Recommended Preventive Services as of July 14, 2010

The materials that follow list recommended preventive services, current as of July 14, 2010, that will have to be covered without cost-sharing when delivered by an in-network provider. In many cases, the recommendations or guidelines went into effect before September 23, 2009; therefore the recommended services must be covered under these interim final regulations in plan years (in the individual market, policy years) that begin on or after September 23, 2010. However, there are some services that appear in the figure that are based on recommendations or guidelines that went into effect at some point later than September 23, 2009. Those services do not have to be covered under these interim final regulations until plan years (in the individual market, policy years) that begin at some point later than September 23, 2010. In addition, there are a few recommendations and guidelines that went into effect after September 23, 2009 and are not included in the figure. In both cases, information at *http://www.HealthCare.gov/center/regulations/prevention.html* specifically identifies those services and the relevant dates. The materials at *http://www.HealthCare.gov/center/regulations/prevention.html* will be updated on an ongoing basis, and will contain the most current recommended preventive services.

A. Recommendations of the United States Preventive Services Task Force (Task Force)

Recommendations of the Task Force appear in a chart that follows. This chart includes a description of the topic, the text of the Task Force recommendation, the grade the recommendation received (A or B), and the date that the recommendation went into effect.

B. Recommendations of the Advisory Committee On Immunization Practices (Advisory Committee) That Have Been Adopted by the Director of the Centers for Disease Control and Prevention

Recommendations of the Advisory Committee appear in four immunization schedules that follow: A schedule for children age 0 to 6 years, a schedule for children age 7 to 18 years, a "catch-up" schedule for children, and a schedule for adults. Immunization schedules are issued every year, and the schedules that appear here are the 2010 schedules. The schedules contain graphics that provide information about the recommended age for vaccination, number of doses needed, interval between the doses, and (for adults) recommendations associated with particular health conditions. In addition to the graphics, the schedules contain detailed footnotes that provide further information on each immunization in the schedule.

C. Comprehensive Guidelines Supported by the Health Resources and Services Administration (HRSA) for Infants, Children, and Adolescents

Comprehensive guidelines for infants, children, and adolescents supported by HRSA appear in two charts that follow: The Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care, and the Uniform Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

BILLING CODE 4830–01–P; 4510–29–P; 4210–01–P

Grade A and B Recommendations of the United States Preventive Services Task Force - July 13, 2010

Topic	Text	Grade	Date In Effect
Screening for abdominal aortic aneurysm	The USPSTF recommends one-time screening for abdominal aortic aneurysm (AAA) by ultrasonography in men aged 65 to 75 who have ever smoked.	B	February 28, 2005
Counseling for alcohol misuse	The U.S. Preventive Services Task Force (USPSTF) recommends screening and behavioral counseling interventions to reduce alcohol misuse (go to Clinical Considerations) by adults, including pregnant women, in primary care settings.	B	April 30, 2004
Screening for anemia	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B	May 31, 2006
Aspirin to prevent CVD: men	The USPSTF recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.	A	March 30, 2009
Aspirin to prevent CVD: women	The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	A	March 30, 2009
Screening for bacteriuria	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A	July 31, 2008
Screening for blood pressure	The U.S. Preventive Services Task Force (USPSTF) recommends screening for high blood pressure in adults aged 18 and older.	A	December 31, 2007
Counseling for BRCA screening	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.	B	September 30, 2005
Screening for breast cancer (mammography)	The USPSTF recommends screening mammography for women with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older.	B	September 30, 2002
Chemoprevention of breast cancer	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B	July 31, 2002
Counseling for breast feeding	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B	October 31, 2008
Screening for cervical cancer	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	B	January 31, 2003
Screening for chlamydial infection: non-pregnant women	The U.S. Preventive Services Task Force (USPSTF) recommends screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk.	A	June 30, 2007
Screening for chlamydial infection: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B	June 30, 2007

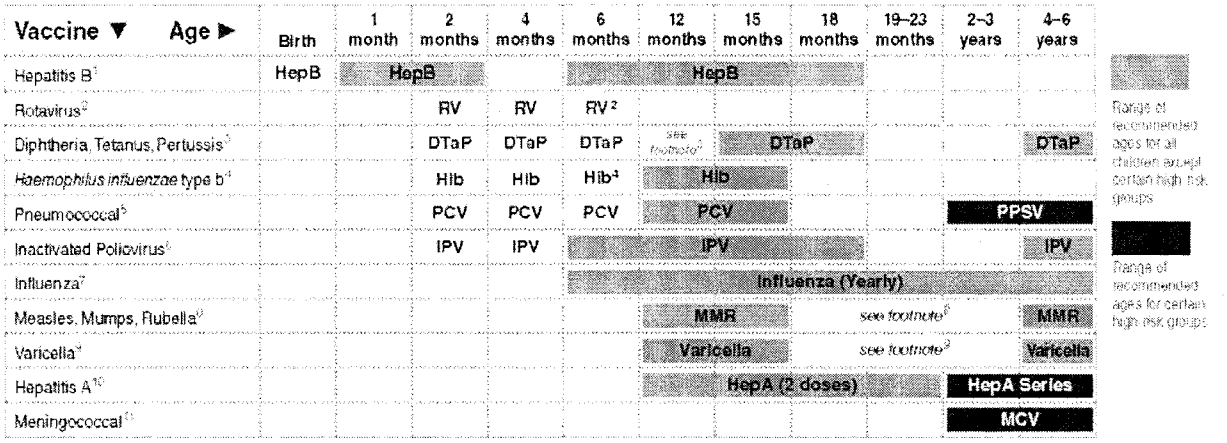
Screening for cholesterol abnormalities: men 35 and older	The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening men aged 35 and older for lipid disorders.	A	June 30, 2008
Screening for cholesterol abnormalities: men younger than 35	The USPSTF recommends screening men aged 20 to 35 for lipid disorders if they are at increased risk for coronary heart disease.	B	June 30, 2008
Screening for cholesterol abnormalities: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A	June 30, 2008
Screening for cholesterol abnormalities: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B	June 30, 2008
Screening for colorectal cancer	The USPSTF recommends screening for colorectal cancer (CRC) using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A	October 31, 2008
Chemoprevention of dental caries	The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride.	B	April 30, 2004
Screening for depression: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B	December 31, 2009, identical to a 2002 recommendation
Screening for depression: adolescents	The USPSTF recommends screening of adolescents (12-18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B	March 30, 2009
Screening for diabetes	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B	June 30, 2008
Counseling for diet	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B	January 30, 2003
Supplementation with folic acid	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A	May 31, 2009
Screening for gonorrhea: women	The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors, go to Clinical Considerations for further discussion of risk factors).	B	May 31, 2005
Prophylactic medication for gonorrhea: newborns	The USPSTF strongly recommends prophylactic ocular topical medication for all newborns against gonococcal ophthalmia neonatorum.	A	May 31, 2005

Screening for hearing loss	The USPSTF recommends screening for hearing loss in all newborn infants.	B	July 31, 2008
Screening for hemoglobinopathies	The U. S. Preventive Services Task Force (USPSTF) recommends screening for sickle cell disease in newborns.	A	September 30, 2007
Screening for hepatitis B	The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.	A	June 30, 2009
Screening for HIV	The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (go to Clinical Considerations for discussion of risk factors).	A	July 31, 2005
Screening for congenital hypothyroidism	The USPSTF recommends screening for congenital hypothyroidism (CH) in newborns.	A	March 31, 2008
Iron supplementation in children	The U.S. Preventive Services Task Force (USPSTF) recommends routine iron supplementation for asymptomatic children aged 6 to 12 months who are at increased risk for iron deficiency anemia (go to Clinical Considerations for a discussion of increased risk).	B	May 30, 2006
Screening and counseling for obesity: adults	The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.	B	December 31, 2003
Screening and counseling for obesity: children	The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral interventions to promote improvement in weight status.	B	January 31, 2010
Screening for osteoporosis	The U.S. Preventive Services Task Force (USPSTF) recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures. (Go to Clinical Considerations for discussion of women at increased risk.)	B	September 30, 2002
Screening for PKU	The USPSTF recommends screening for phenylketonuria (PKU) in newborns.	A	March 31, 2008
Screening for Rh incompatibility:	The U.S. Preventive Services Task Force (USPSTF) strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A	February 29, 2004
Screening for Rh incompatibility: 24-28 weeks gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24-28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B	February 29, 2004
Counseling for STIs	The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs.	B	October 31, 2008
Counseling for tobacco use: adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A	April 30, 2009
Counseling for tobacco use: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.	A	April 30, 2009

Screening for syphilis: non-pregnant persons	The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A	July 31, 2004
Screening for syphilis: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A	July 31, 2004
Screening for visual acuity in children	The USPSTF recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years.	B	May 31, 2004

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

For those who fall behind or start late, see the catch-up schedule



This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: **http://www.cdc.gov/vaccines/pubs/acip-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**.

1. **Hepatitis B vaccine (HepB).** (Minimum age: birth)
   At birth:
   - Administer monovalent HepB to all newborns before hospital discharge.
   - If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
   - If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if HBsAg-positive, administer HBIG (no later than age 1 week).

   After the birth dose:
   - The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks. The final dose should be administered no earlier than age 24 weeks.
   - Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg 1 to 2 months after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit).
   - Administration of 4 doses of HepB to infants is permissible when a combination vaccine containing HepB is administered after the birth dose. The fourth dose should be administered no earlier than age 24 weeks.
2. **Rotavirus vaccine (RV).** (Minimum age: 6 weeks)
   - Administer the first dose at age 6 through 14 weeks (maximum age: 14 weeks 6 days). Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months 0 days.
   - If Rotarix is administered at ages 2 and 4 months, a dose at 6 months is not indicated.
3. **Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).** (Minimum age: 6 weeks)
   - The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
   - Administer the final dose in the series at age 4 through 6 years.
4. ***Haemophilus influenzae* type b conjugate vaccine (Hib).** (Minimum age: 6 weeks)
   - If PRP-OMP (PedvaxHIB or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
   - TriHiBit (DTaP/Hib) and Hiberix (PRP-T) should not be used for doses at ages 2, 4, or 6 months for the primary series but can be used as the final dose in children aged 12 months through 4 years.
5. **Pneumococcal vaccine.** (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])
   - PCV is recommended for all children aged younger than 5 years. Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
   - Administer PPSV 2 or more months after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. See *MMWR* 1997;46(No. RR-8).
6. **Inactivated poliovirus vaccine (IPV)** (Minimum age: 6 weeks)
   - The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
   - If 4 doses are administered prior to age 4 years a fifth dose should be administered at age 4 through 6 years. See *MMWR* 2009;58(30):829–30.
7. **Influenza vaccine (seasonal).** (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])
   - Administer annually to children aged 6 months through 18 years.
   - For healthy children aged 2 through 6 years (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used, except LAIV should not be given to children aged 2 through 4 years who have had wheezing in the past 12 months.
   - Children receiving TIV should receive 0.25 mL if aged 6 through 35 months or 0.5 mL if aged 3 years or older.
   - Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
   - For recommendations for use of influenza A (H1N1) 2009 monovalent vaccine see *MMWR* 2009;58(No. RR-10).
8. **Measles, mumps, and rubella vaccine (MMR).** (Minimum age: 12 months)
   - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.
9. **Varicella vaccine.** (Minimum age: 12 months)
   - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
   - For children aged 12 months through 12 years the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
10. **Hepatitis A vaccine (HepA).** (Minimum age: 12 months)
    - Administer to all children aged 1 year (i.e., aged 12 through 23 months). Administer 2 doses at least 6 months apart.
    - Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits.
    - HepA also is recommended for older children who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
11. **Meningococcal vaccine.** (Minimum age: 2 years for meningococcal conjugate vaccine [MCV4] and for meningococcal polysaccharide vaccine [MPSV4])
    - Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.
    - Administer MCV4 to children previously vaccinated with MCV4 or MPSV4 after 3 years if first dose administered at age 2 through 6 years. See *MMWR* 2009;58:1042–3.

The Recommended Immunization Schedules for Persons Aged 0 through 18 Years are approved by the Advisory Committee on Immunization Practices (**http://www.cdc.gov/vaccines/recs/acip**), the American Academy of Pediatrics (**http://www.aap.org**), and the American Academy of Family Physicians (**http://www.aafp.org**).

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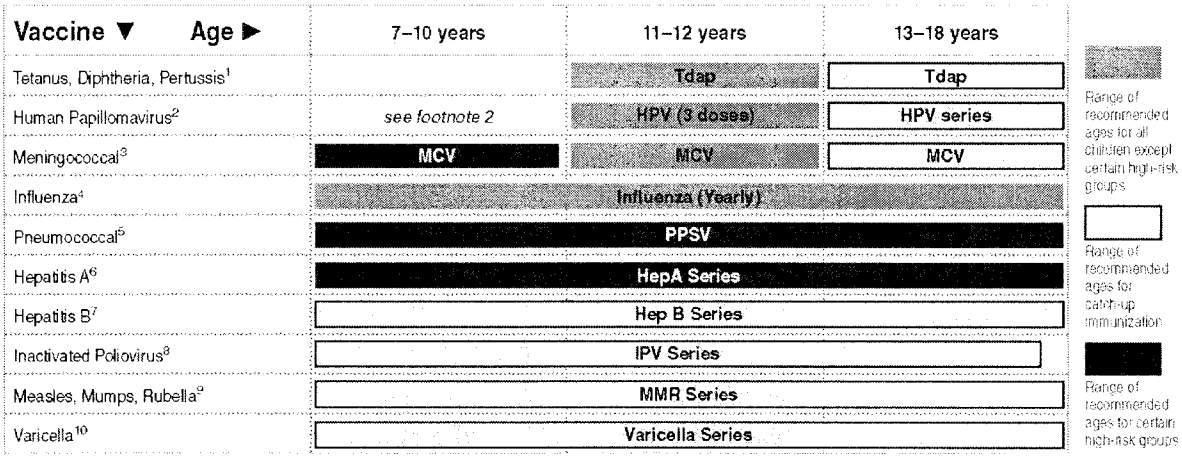
Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2010

For those who fall behind or start late, see the schedule below and the catch-up schedule



This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: **http://www.cdc.gov/vaccines/pubs/acip-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**.

1. **Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).** (Minimum age: 10 years for Boostrix and 11 years for Adacel)
   - Administer at age 11 or 12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoid (Td) booster dose.
   - Persons aged 13 through 18 years who have not received Tdap should receive a dose.
   - A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose; however, a shorter interval may be used if pertussis immunity is needed.
2. **Human papillomavirus vaccine (HPV).** (Minimum age: 9 years)
   - Two HPV vaccines are licensed: a quadrivalent vaccine (HPV4) for the prevention of cervical, vaginal and vulvar cancers (in females) and genital warts (in females and males), and a bivalent vaccine (HPV2) for the prevention of cervical cancers in females.
   - HPV vaccines are most effective for both males and females when given before exposure to HPV through sexual contact.
   - HPV4 or HPV2 is recommended for the prevention of cervical precancers and cancers in females.
   - HPV4 is recommended for the prevention of cervical, vaginal and vulvar precancers and cancers and genital warts in females.
   - Administer the first dose to females at age 11 or 12 years.
   - Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
   - Administer the series to females at age 13 through 18 years if not previously vaccinated.
   - HPV4 may be administered in a 3-dose series to males aged 9 through 18 years to reduce their likelihood of acquiring genital warts.
3. **Meningococcal conjugate vaccine (MCV4).**
   - Administer at age 11 or 12 years, or at age 13 through 18 years if not previously vaccinated.
   - Administer to previously unvaccinated college freshmen living in a dormitory.
   - Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, or certain other conditions placing them at high risk.
   - Administer to children previously vaccinated with MCV4 or MPSV4 who remain at increased risk after 3 years (if first dose administered at age 2 through 6 years) or after 5 years (if first dose administered at age 7 years or older). Persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose. See *MMWR* 2009;58:1042–3.
4. **Influenza vaccine (seasonal).**
   - Administer annually to children aged 6 months through 18 years.
   - For healthy nonpregnant persons aged 7 through 18 years (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used.
   - Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
   - For recommendations for use of influenza A (H1N1) 2009 monovalent vaccine, See *MMWR* 2009;58(No. RR-10).
5. **Pneumococcal polysaccharide vaccine (PPSV).**
   - Administer to children with certain underlying medical conditions, including a cochlear implant. A single revaccination should be administered after 5 years to children with functional or anatomic asplenia or an immunocompromising condition. See *MMWR* 1997;46(No. RR-8).
6. **Hepatitis A vaccine (HepA).**
   - Administer 2 doses at least 6 months apart.
   - HepA is recommended for children aged older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
7. **Hepatitis B vaccine (HepB).**
   - Administer the 3-dose series to those not previously vaccinated.
   - A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB is licensed for children aged 11 through 15 years.
8. **Inactivated poliovirus vaccine (IPV).**
   - The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
   - If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
9. **Measles, mumps, and rubella vaccine (MMR).**
   - If not previously vaccinated, administer 2 doses or the second dose for those who have received only 1 dose, with at least 28 days between doses.
10. **Varicella vaccine.**
    - For persons aged 7 through 18 years without evidence of immunity (see *MMWR* 2007;56[No. RR-4]), administer 2 doses if not previously vaccinated or the second dose if only 1 dose has been administered.
    - For persons aged 7 through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
    - For persons aged 13 years and older, the minimum interval between doses is 28 days.

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The Recommended Immunization Schedules for Persons Aged 0 through 18 Years are approved by the Advisory Committee on Immunization Practices (**http://www.cdc.gov/vaccines/recs/acip**), the American Academy of Pediatrics (**http://www.aap.org**), and the American Academy of Family Physicians (**http://www.aafp.org**).

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Catch-up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Who Are More Than 1 Month Behind—United States • 2010

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
PERSONS AGED 4 MONTHS THROUGH 6 YEARS					
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Rotavirus[2]	6 wks	4 weeks	4 weeks[2]		
Diphtheria, Tetanus, Pertussis[3]	6 wks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[4]	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[4] if current age is younger than 12 months 8 weeks (as final dose)[4] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months	
Pneumococcal[5]	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months or for high-risk children who received 3 doses at any age	
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months			
Hepatitis A[9]	12 mos	6 months			
PERSONS AGED 7 THROUGH 18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis[10]	7 yrs[10]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human Papillomavirus[11]	9 yrs	Routine dosing intervals are recommended[11]			
Hepatitis A[9]	12 mos	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

1. **Hepatitis B vaccine (HepB).**
   - Administer the 3-dose series to those not previously vaccinated.
   - A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB is licensed for children aged 11 through 15 years.
2. **Rotavirus vaccine (RV).**
   - The maximum age for the first dose is 14 weeks 6 days. Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months 0 days.
   - If Rotarix was administered for the first and second doses, a third dose is not indicated.
3. **Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).**
   - The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
4. ***Haemophilus influenzae* type b conjugate vaccine (Hib).**
   - Hib vaccine is not generally recommended for persons aged 5 years or older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in persons who have sickle cell disease, leukemia, or HIV infection, or who have had a splenectomy; administering 1 dose of Hib vaccine to these persons who have not previously received Hib vaccine is not contraindicated.
   - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
   - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months.
5. **Pneumococcal vaccine.**
   - Administer 1 dose of pneumococcal conjugate vaccine (PCV) to all healthy children aged 24 through 59 months who have not received at least 1 dose of PCV on or after age 12 months.
   - For children aged 24 through 59 months with underlying medical conditions, administer 1 dose of PCV if 3 doses were received previously or administer 2 doses of PCV at least 8 weeks apart if fewer than 3 doses were received previously.
   - Administer pneumococcal polysaccharide vaccine (PPSV) to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant, at least 8 weeks after the last dose of PCV. See *MMWR* 1997;46(No. RR-8).
6. **Inactivated poliovirus vaccine (IPV).**
   - The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
   - A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months following the previous dose.
   - In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
7. **Measles, mumps, and rubella vaccine (MMR).**
   - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.
   - If not previously vaccinated, administer 2 doses with at least 28 days between doses.
8. **Varicella vaccine.**
   - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
   - For persons aged 12 months through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
   - For persons aged 13 years and older, the minimum interval between doses is 28 days.
9. **Hepatitis A vaccine (HepA).**
   - HepA is recommended for children aged older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
10. **Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).**
    - Doses of DTaP are counted as part of the Td/Tdap series
    - Tdap should be substituted for a single dose of Td in the catch-up series or as a booster for children aged 10 through 18 years; use Td for other doses.
11. **Human papillomavirus vaccine (HPV).**
    - Administer the series to females at age 13 through 18 years if not previously vaccinated.
    - Use recommended routine dosing intervals for series catch-up (i.e., the second and third doses should be administered at 1 to 2 and 6 months after the first dose). The minimum interval between the first and second doses is 4 weeks. The minimum interval between the second and third doses is 12 weeks, and the third dose should be administered at least 24 weeks after the first dose.

Information about reporting reactions after immunization is available online at **http://www.vaers.hhs.gov** or by telephone, **800-822-7967**. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at **http://www.cdc.gov/vaccines** or telephone, **800-CDC-INFO** (800-232-4636).

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Recommended Adult Immunization Schedule

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Note: These recommendations *must* be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group

VACCINE ▼ / AGE GROUP ▶	19–26 years	27–49 years	50–59 years	60–64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap)[1,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs				Td booster every 10 yrs
Human papillomavirus (HPV)[2,*]	3 doses (females)				
Varicella[3,*]	2 doses				
Zoster[4,*]				1 dose	
Measles, mumps, rubella (MMR)[5,*]	1 or 2 doses		1 dose		
Influenza[6,*]	1 dose annually				
Pneumococcal (polysaccharide)[7,*]	1 or 2 doses				1 dose
Hepatitis A[8,*]	2 doses				
Hepatitis B[9,*]	3 doses				
Meningococcal[11,*]	1 or more doses				

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Figure 2. Vaccines that might be indicated for adults based on medical and other indications

VACCINE ▼ / INDICATION ▶	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV])[1,2,3]	HIV infection[1,2,3] CD4+ T lymphocyte count <200 cells/μL	HIV infection[1,2,3] CD4+ T lymphocyte count ≥200 cells/μL	Diabetes, heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Tetanus, diphtheria, pertussis (Td/Tdap)[1,2]	Td	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs							
Human papillomavirus (HPV)[2,4]	3 doses for females through age 26 yrs								
Varicella[2,5]	Contraindicated	2 doses							
Zoster[4]	Contraindicated	1 dose							
Measles, mumps, rubella (MMR)[2,5]	Contraindicated	1 or 2 doses							
Influenza[2,5]	1 dose TIV annually								1 dose TIV or LAIV annually
Pneumococcal (polysaccharide)[2,6]	1 or 2 doses								
Hepatitis A[2,7]	2 doses								
Hepatitis B[2,8]	3 doses								
Meningococcal[2,9]	1 or more doses								

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older as of January 1, 2010. Licensed combination vaccines may be used whenever any component of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are licensed during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm)

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Footnotes

Recommended Adult Immunization Schedule—UNITED STATES · 2010

For complete statements by the Advisory Committee on Immunization Practices (ACIP), visit www.cdc.gov/vaccines/pubs/ACIP-list.htm.

1. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

Tdap should replace a single dose of Td for adults aged 19 through 64 years who have not received a dose of Tdap previously.

Adults with uncertain or incomplete history of primary vaccination series with tetanus and diphtheria toxoid–containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid–containing vaccines, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid–containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received ≥10 years previously. Tdap or Td vaccine may be used, as indicated.

If a woman is pregnant and received the last Td vaccination ≥10 years previously, administer Td during the second or third trimester. If the woman received the last Td vaccination <10 years previously, administer Tdap during the immediate postpartum period. A dose of Tdap is recommended for postpartum women, close contacts of infants aged <12 months, and all health-care personnel with direct patient contact if they have not previously received Tdap. An interval as short as 2 years from the last Td is suggested, shorter intervals can be used. Td may be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be administered instead of Td to a pregnant woman.

Consult the ACIP statement for recommendations for giving Td as prophylaxis in wound management.

2. Human papillomavirus (HPV) vaccination

HPV vaccination is recommended at age 11 or 12 years with catch-up vaccination at ages 13 through 26 years.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated consistent with age-based recommendations. Sexually active females who have not been infected with any of the four HPV vaccine types (types 6, 11, 16, 18 all of which HPV2 prevents) or any of the two HPV vaccine types (types 16 and 18 both of which HPV2 prevents) receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types. HPV4 or HPV2 can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test, because these conditions are not evidence of prior infection with all vaccine HPV types.

HPV4 may be administered to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. HPV4 would be most effective when administered before exposure to HPV through sexual contact.

A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose.

Although HPV vaccination is not specifically recommended for persons with the medical indications described in Figure 2, "Vaccines that might be indicated for adults based on medical and other indications," it may be administered to these persons because the HPV vaccine is not a live-virus vaccine. However, the immune response and vaccine efficacy might be less for persons with the medical indications described in Figure 2 than in persons who do not have the medical indications described or who are immunocompetent. Health-care personnel are not at increased risk because of occupational exposure, and should be vaccinated consistent with age-based recommendations.

3. Varicella vaccination

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine if not previously vaccinated or the second dose if they have received only 1 dose, unless they have a medical contraindication. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or 2) are at high risk for exposure or transmission (e.g., teachers; child-care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health care provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link with a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.

4. Herpes zoster vaccination

A single dose of zoster vaccine is recommended for adults aged ≥60 years regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication.

5. Measles, mumps, rubella (MMR) vaccination

Adults born before 1957 generally are considered immune to measles and mumps.

Measles component: Adults born during or after 1957 should receive 1 or more doses of MMR vaccine unless they have 1) a medical contraindication; 2) documentation of vaccination with 1 or more doses of MMR vaccine; 3) laboratory evidence of immunity; or 4) documentation of physician-diagnosed measles.

A second dose of MMR vaccine, administered 4 weeks after the first dose, is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been vaccinated previously with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

Mumps component: Adults born during or after 1957 should receive 1 dose of MMR vaccine unless they have 1) a medical contraindication; 2) documentation of vaccination with 1 or more doses of MMR vaccine; 3) laboratory evidence of immunity; or 4) documentation of physician-diagnosed mumps.

A second dose of MMR vaccine, administered 4 weeks after the first dose, is recommended for adults who 1) live in a community experiencing a mumps outbreak and are in an affected age group; 2) are students in postsecondary educational institutions; 3) work in a health care facility; or 4) plan to travel internationally.

Rubella component: 1 dose of MMR vaccine is recommended for women who do not have documentation of rubella vaccination, or who lack laboratory evidence of immunity, for women of childbearing age, regardless of birth year. Rubella immunity should be determined and women should be counseled regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

Health-care personnel born before 1957: For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval (for measles and mumps) and 1 dose of MMR vaccine (for rubella), respectively.

During outbreaks, health-care facilities should recommend that unvaccinated health-care personnel born before 1957, who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, receive 2 doses of MMR vaccine during an outbreak of measles or mumps, and 1 dose during an outbreak of rubella.

Complete information about evidence of immunity is available at www.cdc.gov/vaccines/recs/provisional/default.htm.

6. Seasonal influenza vaccination

Vaccinate all persons aged ≥50 years and any younger persons who would like to decrease their risk of getting influenza. Vaccinate persons aged 19 through 49 years with any of the following indications.

Medical: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus; renal or hepatic dysfunction, hemoglobinopathies, or immunocompromising conditions (including immunocompromising conditions caused by medications or HIV); cognitive, neurologic or neuromuscular disorders; and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational: All health-care personnel, including those employed by long-term care and assisted-living facilities, and caregivers of children aged <5 years.

Other: Residents of nursing homes and other long-term care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged <5 years, persons aged ≥50 years, and persons of all ages with high-risk conditions).

Healthy, nonpregnant adults aged <50 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special-care units may receive either intranasally administered live, attenuated influenza vaccine (LAIV) or inactivated vaccine. Other persons should receive the inactivated vaccine.

7. Pneumococcal polysaccharide (PPSV) vaccination

Vaccinate all persons with the following indications.

Medical: Chronic lung disease (including asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, cirrhosis; chronic alcoholism; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunocompromising conditions including chronic renal failure or nephrotic syndrome; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other: Residents of nursing homes or long-term care facilities and persons who smoke cigarettes. Routine use of PPSV is not recommended for American Indians/Alaska Natives or persons aged <65 years unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for American Indians/Alaska Natives and persons aged 50 through 64 years who are living in areas where the risk for invasive pneumococcal disease is increased.

8. Revaccination with PPSV

One time revaccination after 5 years is recommended for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions. For persons aged ≥65 years, one-time revaccination is recommended if they were vaccinated ≥5 years previously and were younger than aged <65 years at the time of primary vaccination.

9. Hepatitis A vaccination

Vaccinate persons with any of the following indications and any person seeking protection from hepatitis A virus (HAV) infection.

Behavioral: Men who have sex with men and persons who use injection drugs.

Occupational: Persons working with HAV-infected primates or with HAV in a research laboratory setting.

Medical: Persons with chronic liver disease and persons who receive clotting factor concentrates.

Other: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at www.cdc.gov/travel/contentDiseases.aspx).

Unvaccinated persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days after arrival of the adoptee in the United States should consider vaccination. The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally ≥2 weeks before the arrival of the adoptee.

Single-antigen vaccine formulations should be administered in a 2 dose schedule at either 0 and 6–12 months (Havrix), or 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.

10. Hepatitis B vaccination

Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection.

Behavioral: Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men.

Occupational: Health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

Medical: Persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease.

Other: Household contacts and sex partners of persons with chronic HBV infection; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at www.cdc.gov/travel/contentDiseases.aspx).

Hepatitis B vaccination is recommended for all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug abuse treatment and prevention services; health care settings targeting services to injection drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.

Administer or complete a 3-dose series of HepB to those persons not previously vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be administered at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.

Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 μg/mL (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 μg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2 and 6 months.

11. Meningococcal vaccination

Meningococcal vaccine should be administered to persons with the following indications.

Medical: Adults with anatomic or functional asplenia, or persistent complement component deficiencies.

Other: First year college students living in dormitories, microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December through June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine (MCV4) is preferred for adults with any of the preceding indications who are aged ≤55 years. meningococcal polysaccharide vaccine (MPSV4) is preferred for adults aged ≥56 years. Revaccination with MCV4 after 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia). Persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose.

12. Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

Hib vaccine generally is not recommended for persons aged ≥5 years. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had a splenectomy. Administering 1 dose of Hib vaccine to these high-risk persons who have not previously received Hib vaccine is not contraindicated.

13. Immunocompromising conditions

Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, influenza [inactivated influenza vaccine]) and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at www.cdc.gov/Vaccines/pubs/acip-list.htm.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Recommendations for Preventive Pediatric Health Care

Bright Futures/American Academy of Pediatrics

Bright Futures

Each child and family is unique; therefore, these Recommendations for Preventive Pediatric Health Care are designed for the care of children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in a socially supportive milieu. Modifications may become necessary if circumstances suggest variations from normal.

Developmental, psychosocial, and chronic disease issues for children and adolescents may require more frequent counseling and treatment visits separate from preventive health visits.

These guidelines represent a consensus by the American Academy of Pediatrics (AAP) and Bright Futures. The AAP continues to emphasize the great importance of continuity of care in comprehensive health supervision and the need to avoid fragmentation of care.

AGE	INFANCY						EARLY CHILDHOOD						MIDDLE CHILDHOOD					ADOLESCENCE					
	PRENATAL[1]	NEWBORN[2]	3-5 d	1 mo	2 mo	4 mo	6 mo	9 mo	12 mo	15 mo	18 mo	24 mo	30 mo	3 y	4 y	5 y	6 y	7 y	8 y	9 y	10 y	11 y	12 y	13 y	14 y	15 y	16 y	17 y	18 y	19 y	20 y	21 y
HISTORY																																
Initial/Interval	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
MEASUREMENTS																																
Length/Height and Weight	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Head Circumference	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Weight for Length	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Body Mass Index																																
Blood Pressure[3]			★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★	★
SENSORY SCREENING																																
Vision	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Hearing	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
DEVELOPMENTAL/BEHAVIORAL ASSESSMENT																																
Developmental Screening[4]							•		•																							
Autism Screening											•	•																				
Developmental Surveillance	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Psychosocial/Behavioral Assessment	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Alcohol and Drug Use Assessment																																
PHYSICAL EXAMINATION[5]	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
PROCEDURES[6]																																
Newborn Metabolic/Hemoglobin Screening[7]	◄	•																														
Immunization[8]		•	•		•		•		•		•		•		•		•		•		•		•		•		•		•		•	
Hematocrit or Hemoglobin[9]									★				★		★		★		★		★		★		★		★		★		★	
Lead Screening[10]									★				★		★		★		★		★		★		★		★		★		★	
Tuberculin Test[11]					★					★																						
Dyslipidemia Screening[12]													★		★		★		★		★		★		★		★		★		★	
STI Screening[13]																																
Cervical Dysplasia Screening[14]																																
ORAL HEALTH[15]							★	★	★																							
ANTICIPATORY GUIDANCE[16]	•		•		•		•		•		•		•		•		•		•		•		•		•		•		•		•	

KEY

• = to be performed ★ = risk assessment to be performed, with appropriate action to follow, if positive ◄ ► = range during which a service may be provided, with the symbol indicating the preferred age

SACHDNC Recommended Uniform Screening Panel[1]
CORE[2] CONDITIONS[3]
(as of February 2010)

ACMG Code	Core Condition	Metabolic Disorder			Endocrine Disorder	Hemoglobin Disorder	Other Disorder
		Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders			
PROP	Propionic academia						
MUT	Methylmalonic acidemia (methylmalonyl-CoA mutase)						
Cbl A,B	Methylmalonic acidemia (cobalamin disorders)						
IVA	Isovaleric acidemia						
3-MCC	3-Methylcrotonyl-CoA carboxylase deficiency						
HMG	3-Hydroxy-3-methyglutaric aciduria						
MCD	Holocarboxylase synthase deficiency						
ßKT	ß-Ketothiolase deficiency						
GA1	Glutaric acidemia type I						
CUD	Carnitine uptake defect/carnitine transport defect						
MCAD	Medium-chain acyl-CoA dehydrogenase deficiency						
VLCAD	Very long-chain acyl-CoA dehydrogenase deficiency						
LCHAD	Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency						
TFP	Trifunctional protein deficiency						
ASA	Argininosuccinic aciduria						
CIT	Citrullinemia, type I						
MSUD	Maple syrup urine disease						
HCY	Homocystinuria						
PKU	Classic phenylketonuria						
TYR I	Tyrosinemia, type I						
CH	Primary congenital hypothyroidism						
CAH	Congenital adrenal hyperplasia						
Hb SS	S,S disease (Sickle cell anemia)						
Hb S/ßTh	S, βeta-thalassemia						
Hb S/C	S,C disease						
BIOT	Biotinidase deficiency						
GALT	Classic galactosemia						
SCID	Severe Combined Immunodeficiences						
CF	Cystic fibrosis						
HEAR	Hearing loss						

1. The selection of these conditions is based on the report "Newborn Screening: Towards a Uniform Screening Panel and System. Genet Med. 2006; 8(5) Suppl: S12-S252" as authored by the American College of Medical Genetics (ACMG) and commissioned by the Health Resources and Services Administration (HRSA).
2. Disorders that should be included in every Newborn Screening Program
3. The Nomenclature for Conditions is based on the report "Naming and Counting Disorders (Conditions) Included in Newborn Screening Panels" Pediatrics 2006; 117 (5) Suppl: S308-S314

SACHDNC Recommended Uniform Screening Panel[1]
SECONDARY[2] CONDITIONS [3]
(as of February 2010)

ACMG Code	Secondary Condition	Metabolic Disorder			Hemoglobin Disorder	Other Disorder
		Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders		
Cbl C,D	Methylmalonic acidemia with homocystinuria					
MAL	Malonic acidemia					
IBG	Isobutyrylglycinuria					
2MBG	2-Methylbutyrylglycinuria					
3MGA	3-Methylglutaconic aciduria					
2M3HBA	2-Methyl-3-hydroxybutyric aciduria					
SCAD	Short-chain acyl-CoA dehydrogenase deficiency					
M/SCHAD	Medium/short-chain L-3-hydroxyacl-CoA dehydrogenase deficiency					
GA2	Glutaric acidemia type II					
MCAT	Medium-chain ketoacyl-CoA thiolase deficiency					
DE RED	2,4 Dienoyl-CoA reductase deficiency					
CPT IA	Carnitine palmitoyltransferase type I deficiency					
CPT II	Carnitine palmitoyltransferase type II deficiency					
CACT	Carnitine acylcarnitine translocase deficiency					
ARG	Argininemia					
CIT II	Citrullinemia, type II					
MET	Hypermethioninemia					
H-PHE	Benign hyperphenylalaninemia					
BIOPT (BS)	Biopterin defect in cofactor biosynthesis					
BIOPT (REG)	Biopterin defect in cofactor regeneration					
TYR II	Tyrosinemia, type II					
TRY III	Tyrosinemia, type III					
Var Hb	Various other hemoglobinopathies					
GALE	Galactoepimerase deficiency					
GALK	Galactokinase deficiency					
	T-cell related lymphocyte deficiencies					

1. The selection of these conditions is based on the report "Newborn Screening: Towards a Uniform Screening Panel and System. Genet Med. 2006; 8(5) Suppl: S12-S252" as authored by the American College of Medical Genetics (ACMG) and commissioned by the Health Resources and Services Administration (HRSA).

2. Disorders that can be detected in the differential diagnosis of a core disorder

3. The Nomenclature for Conditions is based on the report "Naming and Counting Disorders (Conditions) Included in Newborn Screening Panels" Pediatrics 2006; 117 (5) Suppl: S308-S314

BILLING CODE 4830–01–C; 4510–29–C; 4210–01–C

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 8, 2010

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 9th day of July, 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: July 9, 2010

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: July 9, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter 1

■ Accordingly, 26 CFR Part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9815–2713T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–2713T also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-

billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Effective/applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

(e) *Expiration date.* This section expires on *July 12, 2013* or on such earlier date as may be provided in final regulations or other action published in the **Federal Register.**

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

■ 29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for Part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

Subpart C—Other Requirements

■ 2. Section 2590.715–2713 is added to subpart C to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been

adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 2590.715–1251 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147, added May 13, 2010, at 75 FR 27138, effective July 12, 2010, as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Sections 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Add § 147.130 to read as follows:

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A

plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

[FR Doc. 2010–17242 Filed 7–14–10; 11:15 am]

BILLING CODE 4830–01–P; 4510–29–P; 4210–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0646]

RIN 1625–AA00

Safety Zone; Transformers 3 Movie Filming, Chicago River, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Chicago River near Chicago, Illinois. This zone is intended to restrict vessels from a portion of the Chicago River due to the filming of a major motion picture. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the different types of stunts that will be performed during the filming of this movie.

DATES: *Effective Date:* this rule is effective in the CFR from July 19, 2010 until 9 p.m. on July 19, 2010. This rule is effective with actual notice for purposes of enforcement beginning 7 a.m. on July 16, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0646 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0646 in the "Keyword" box, and then clicking "search." They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, contact or email BM1 Adam Kraft, U.S. Coast Guard Sector Lake Michigan, at 414–747–7154 or *Adam.D.Kraft@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when an agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to the fact that the application for this event was not submitted to our office in time to allow for publishing an NPRM. Based on the hazards associated with the filming of this major motion picture, delaying the publication of this rule to provide for a comment would be contrary to public interest as immediate action is necessary to protect the public.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because delaying the effective date would be contrary to the public interest since immediate action is needed to protect the public and the event would be over by the time the 30 day period is completed.

Basis and Purpose

This temporary safety zone is necessary to protect vessels from the hazards associated with the filming of the major motion picture, Transformers 3. The combination of congested waterways and the filming of dangerous stunts taking place on or near the water pose serious risks of injury to persons and property. As such, the Captain of the Port, Sector Lake Michigan, has determined that the filming of this motion picture does pose significant risks to public safety and property and that a temporary safety zone is necessary.

Discussion of Rule

The safety zone will encompass all U.S. navigable waters of the Chicago River between the Michigan Avenue Bridge, 41°53′20″ N. 087°37′27″ W. and the North Columbus Drive Bascule Bridge, 41°53′19″ N. 087°37′13″ W. [DATUM: NAD 83].

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

commodity pools and other collective investment vehicles ("CIV"), and omnibus accounts and any accounts trading on an undisclosed basis. Disclosure shall be made equally for accounts representing U.S. and non-U.S. entities and natural persons. *Provided however,* that if an ultimate beneficial owner's ownership share of a CIV is less than 10 percent of the CIV's net asset value, as defined in Commission Regulation 4.10, then the ultimate beneficial owner need not be reported.

(e) *Form, time, and manner of filing reports; uniform protocol required.* Each reporting entity shall submit its OCR in the time, manner, and format required by the Commission or its designee. Reporting entities shall adopt a single, uniform protocol, acceptable to the Commission, for the technical structure of the OCR.

(f) *Protection of OCR data.* Each Reporting entity shall segregate any information provided by its root data sources, if such data is provided in furtherance of the Commission's OCR requirements and not otherwise required to be provided by the reporting entity ("protected data"). Reporting entities must ensure that protected data is used only for regulatory or enforcement purposes such as trade practice surveillance, market surveillance, audit, investigation, or rule enforcement. Protected data shall be under the exclusive control of the reporting entity's regulatory compliance department. Reporting entities shall establish appropriate firewall procedures and access controls to ensure the confidentiality, privacy and safekeeping of protected data within their regulatory compliance departments.

Issued in Washington, DC, on July 8, 2010 by the Commission.

David A. Stawick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Concurring Statement of Commissioner O'Malia Regarding the Proposal for the Account Ownership and Control Report

I concur on the release of the Notice of proposed rulemaking related to Account Ownership and Control Report ("OCR"). The Commission must gain greater transparency over the data it receives. The OCR represents a place where technology must catch-up to how trades are executed in the futures markets so critical data ultimately flows to the Commission.

The events of May 6th clearly highlight that technology drives the structure and function of the markets. In order to better understand trading behavior in the derivatives markets, including the trading behaviors of high frequency traders, it is essential to discover who controls which accounts and how those trading styles impact markets, including the order book, which is vital to fulfilling our surveillance and enforcement obligations. CFTC staff recently noted in the preliminary report on the events of May 6th that "obtaining account ownership and control information in the exchange trade registers * * * would increase the timeliness and efficiency of account identification, an essential step in data analysis."[76] The Commission must get as close as possible to real-time surveillance and post-trade transparency; the OCR would move the Commission a step closer to that goal.

Currently, the data the Commission receives from exchanges and other reporting entities lacks information because the Commission has not demanded it. However, I believe the Commission must now demand ownership and control information on all trading accounts in order to enhance the transparency of information reported to the Commission. The proposed rule will allow the Commission to aggregate related trading accounts within and across exchanges in order to better detect abusive trading practices. For example, the OCR will allow the Commission's Division of Market Oversight to identify small and medium sized traders whose open interest does not reach reportable levels, but who can still have deleterious effects on the markets during concentrated periods of intra-day trading. Such intra-day trading scenarios include intra-day position limit violations and "banging the close" manipulations.

The OCR will also bridge the gap between individual transactions reported to the Commission on exchange trade registers and aggregate positions reported to it in large trader data so the Commission can determine how traders established their positions. The OCR will allow the Commission's Office of the Chief Economist to accurately identify and categorize market participants based on their actual trading behavior on a contract-by-contract basis, rather than on how they self-report to the Commission (e.g., registration type or marketing/merchandising activity on CFTC Form 40). In short, the OCR will allow the Commission to better oversee the markets.

Based on the comments received from the Advanced Notice of Proposed Rulemaking published in the **Federal Register** on July 2, 2009, I appreciate that there are concerns regarding the implementation of the OCR for numerous reasons, including the costs and the difficulty of acquiring specific data points. Therefore, it is critical that the Commission engage market participants including exchanges, clearing organizations, futures commission merchants, introducing brokers, and others to understand what data is available and the most effective means by which to acquire this data. I strongly support the modification to this proposed rule to accommodate a staff technical conference to provide market participants an opportunity to provide constructive recommendations as to the most effective means by which the Commission can collect this data.

The proposed financial reform legislation that is currently being negotiated by the Conference Committee will issue a new mandate to the Commission for the oversight of the swaps market. Under the proposed legislation the Commission will be hit with a tsunami of data that will need to be standardized to reflect ownership, control, and other information of the massive over-the-counter (OTC) market. If this legislation is signed into law, the OCR rulemaking, whether in the post-comment or possible implementation phase, will coincide with the Commission's rulemaking efforts under its new mandate. Therefore, I hope to receive comment with respect to the entities (*e.g.,* trade repositories, designated contract markets, or swap execution facilities) from which the Commission should collect OCR data and the product and transaction types for which the Commission should collect data. I hope to receive comment on any additional types of information or data elements related to OTC and swap transactions that should be collected and reported to the Commission. Finally, I am interested in receiving comment on how the derivatives industry could develop and maintain a system to assign unique account identification numbers ("UAIN") to all account owners and account controllers.

On a related issue, I understand that Commission staff is seeking to automate the information collected via CFTC Forms 40 and 102. This process is long overdue and must be accomplished in an expedited fashion. Automation of these forms will minimize the manual entry and cross checking of data and will minimize opportunities for human error. It is my hope that the Commission will release for public comment a proposed rule related to these forms later this summer.

[76] Preliminary Findings Regarding the Market Events of May 6, 2010, Report of the Staffs of the CFTC and SEC to the Joint Advisory Committee on Emerging Regulatory Issues (May 18, 2010).

[FR Doc. 2010–17530 Filed 7–16–10; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–120391–10]

RIN 1545–BJ58

Requirement for Group Health Plans and Health Insurance Issuers To Provide Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: Elsewhere in this issue of the **Federal Register**, the IRS is issuing

temporary regulations under the provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act) regarding preventive health services. The IRS is issuing the temporary regulations at the same time that the Employee Benefits Security Administration of the U.S. Department of Labor and the Office of Consumer Information and Insurance Oversight of the U.S. Department of Health and Human Services are issuing substantially similar interim final regulations with respect to group health plans and health insurance coverage offered in connection with a group health plan under the Employee Retirement Income Security Act of 1974 and the Public Health Service Act. The temporary regulations provide guidance to employers, group health plans, and health insurance issuers providing group health insurance coverage. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by October 18, 2010.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–120391–10), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:PA:LPD:PR (REG–120391–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–120391–10).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Karen Levin at 202–622–6080; concerning submissions of comments, Richard A. Hurst at *Richard.A.Hurst@irscounsel.treas.gov*.

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

The temporary regulations published elsewhere in this issue of the **Federal Register** add § 54.9815–2713T to the Miscellaneous Excise Tax Regulations. The proposed and temporary regulations are being published as part of a joint rulemaking with the Department of Labor and the Department of Health and Human Services (the joint rulemaking). The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information requirement on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are specifically requested on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register.**

Drafting Information

The principal author of these proposed regulations is Karen Levin, Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), IRS. The proposed regulations, as well as the temporary regulations, have been developed in coordination with personnel from the U.S. Department of Labor and the U.S. Department of Health and Human Services.

List of Subjects in 26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 54.9815–2713 also issued under 26 U.S.C. 9833. * * *

Par. 2. Section 54.9815–2713 is added to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

[The text of proposed § 54.9815–2713 is the same as the text of paragraphs (a) through (c) of § 54.9815–2713T published elsewhere in this issue of the **Federal Register**].

Steven Miller

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2010–17243 Filed 7–14–10; 11:15 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 103

RIN 1506–AB07

Amendment to the Bank Secrecy Act Regulations—Definitions and Other Regulations Relating to Prepaid Access

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: FinCEN is extending the comment period for the referenced notice of proposed rulemaking, published June 28, 2010, for an additional thirty (30) days. The original comment period would have expired on July 28, 2010. The new extended comment period will expire on August 27, 2010.

DATES: The comment period for the proposed rule published June 28, 2010, at 75 FR 36589 is extended. Comments must be submitted on or before August 27, 2010.

ADDRESSES: You may submit comments, identified by RIN 1506–AB07, by any of the following methods:

- *Federal E–Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket number TREAS–FinCEN–2009–0007.
- *Mail:* FinCEN, P.O. Box 39, Vienna, VA 22183. Include RIN 1506–AB07 in the body of the text.

however, no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F–9 (§ 239.39 of this chapter)''.

■ 34. Effective December 31, 2012, amend Form 40–F (referenced in 17 CFR 249.240f) by:

■ a. In General Instruction A.(i), removing ''F–9'';

■ b. Removing from paragraph (2)(iv) of General Instruction A. the phrase ''; provided, however, that no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F–9'' and adding in its place the phrase ''or the Registrant filed a Form F–9 with the Commission on or before December 30, 2012''; and

■ c. Revising paragraph (2) of General Instruction C. to read as follows:

(2) Any financial statements, other than interim financial statements, included in this Form by registrants registering securities pursuant to Section 12 of the Exchange Act or reporting pursuant to the provisions of Section 13(a) or 15(d) of the Exchange Act must be reconciled to U.S. GAAP as required by Item 17 of Form 20–F under the Exchange Act, unless this Form is filed with respect to a reporting obligation under Section 15(d) that arose solely as a result of a filing made on Form F–7, F–8, F–9 or F–80, in which case no such reconciliation is required.

Note: The text of Form 40–F does not, and this amendment will not, appear in the Code of Federal Regulations.

Dated: July 27, 2011.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–19421 Filed 8–2–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9541]

RIN 1545–BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS–9992–IFC2]

45 CFR Part 147

RIN 0938–AQ07

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains amendments to the interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

DATES: *Effective date.* These interim final regulations are effective on August 1, 2011.

Comment date. Comments are due on or before September 30, 2011.

Applicability dates. These interim final regulations generally apply to group health plans and group health insurance issuers on August 1, 2011.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. *WARNING:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210–AB44, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: E-OHPSCA2713.EBSA@dol.gov.*
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210–AB44.

Comments received by the Department of Labor will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa*, and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code CMS–9992–IFC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9992–IFC2, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9992–IFC2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the

following addresses prior to the close of the comment period: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–4492 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Internal Revenue Service. Comments to the IRS, identified by REG–120391–10, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail*: CC:PA:LPD:PR (REG–120391–10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- *Hand or courier delivery*: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–120391–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Robert Imes, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (*http://cciio.cms.gov*) and information on health reform can be found at *http://www.HealthCare.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010 (collectively known as the ''Affordable Care Act''). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.[1] The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724[2] (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be ''construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement'' of the Affordable Care Act. Accordingly, State laws that impose requirements on health insurance issuers that are stricter than the requirements imposed by the Affordable Care Act are not superseded by the Affordable Care Act.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated under section 715(a)(1) of ERISA and section 9815(a)(1) of the Code, specifies that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing with respect to:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.[3]

[1] The term ''group health plan'' is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term ''health plan,'' as used in other provisions of title I of the Affordable Care Act. The term ''health plan'' does not include self-insured group health plans.

[2] Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

[3] Under PHS Act section 2713(a)(5), the Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of PHS Act section 2713(a)(1).

• Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be ''in effect'' after it has been adopted by the Director of the Centers for Disease Control and Prevention. A recommendation is considered to be for routine use if it appears on the Immunization Schedules of the Centers for Disease Control and Prevention.

• With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

• With respect to women, preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force), which will be commonly known as HRSA's Women's Preventive Services: Required Health Plan Coverage Guidelines.

The requirements to cover recommended preventive services without any cost-sharing do not apply to grandfathered health plans.[4] The Departments previously issued interim final regulations implementing PHS Act section 2713; these interim final rules were published in the **Federal Register** on July 19, 2010 (75 FR 41726). For the reasons explained below, the Departments are now issuing an amendment to these interim final rules.

II. Overview of the Amendment to the Interim Final Regulations

The interim final regulations provided that a group health plan or health insurance issuer must cover certain items and services, without cost-sharing, as recommended by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the Health Resources and Services Administration. Notably, to the extent not described in the U.S. Preventive Services Task Force recommendations, HRSA was charged with developing comprehensive guidelines for preventive care and screenings with respect to women (*i.e.*, the Women's Preventive Services: Required Health Plan Coverage Guidelines or ''HRSA Guidelines''). The interim final regulations also require that changes in the required items and services be implemented no later than plan years (in the individual market, policy years) beginning on or after the date that is one year from when the new recommendation or guideline is issued.

In response to the request for comments on the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be considered for coverage under PHS Act section 2713(a)(4). Most commenters, including some religious organizations, recommended that HRSA Guidelines include contraceptive services for all women and that this requirement be binding on all group health plans and health insurance issuers with no religious exemption. However, several commenters asserted that requiring group health plans sponsored by religious employers to cover contraceptive services that their faith deems contrary to its religious tenets would impinge upon their religious freedom. One commenter noted that some religious employers do not currently cover such benefits under their group health plan due to their religious beliefs.

The Departments note that PHS Act section 2713(a)(4) gives HRSA the authority to develop comprehensive guidelines for additional preventive care and screenings for women ''for purposes of this paragraph.'' In other words, the statute contemplated HRSA Guidelines that would be developed with the knowledge that certain group health plans and health insurance issuers would be required to cover the services recommended without cost-sharing, unlike the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients. These HRSA Guidelines exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women. In the Departments' view, it is appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the religious beliefs of certain religious employers if coverage of contraceptive services were required in the group health plans in which employees in certain religious positions participate. Specifically, the Departments seek to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions. Such an accommodation would be consistent with the policies of States that require contraceptive services coverage, the majority of which simultaneously provide for a religious accommodation.

In light of the above, the Departments are amending the interim final rules to provide HRSA additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned. The amendment to the interim final rules provides HRSA with the discretion to establish this exemption. Consistent with most States that have such exemptions, as described below, the amended regulations specify that, for purposes of this policy, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization under section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The definition of religious employer, as set forth in the amended regulations, is based on existing definitions used by most States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services. We will be accepting comments on this definition as well as alternative definitions, such as those that have been developed under Title 26 of the United States Code. The definition set forth here is intended to reasonably balance the extension of any coverage of contraceptive services under the HRSA Guidelines to as many women as possible, while respecting the unique relationship between certain religious employers and their employees in certain religious positions. The change in policy effected by this amendment to these interim final rules is intended solely for purposes of PHS Act section 2713 and the companion provisions of ERISA and the Internal Revenue Code.

Because HRSA's discretion to establish an exemption applies only to group health plans sponsored by certain

Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the Task Force prior to those issued in or around November of 2009 (that is, those issued in 2002) will be considered current until new recommendations in this area are issued by the Task Force or appear in comprehensive guidelines supported by HRSA concerning preventive care and screenings for women, which will be commonly known as HRSA's Women's Preventive Services: Required Health Plan Coverage Guidelines.

[4] See 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251 and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

religious employers and group health insurance offered in connection with such plans, health insurance issuers in the individual health insurance market would not be covered under any such exemption.

III. Interim Final Regulations and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815. The amendments promulgated in this rulemaking carry out the provisions of these statutes. Therefore, the foregoing interim final rule authority applies to these amendments.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551, *et seq.*), while a general notice of proposed rulemaking and an opportunity for public comment is generally required before promulgation of regulations, an exception is made when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority to issue interim final rules granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if the APA requirements for notice and comment were applicable to these regulations, they have been satisfied. This is because the Secretaries find that providing for an additional opportunity for public comment is unnecessary, as the July 19, 2010 interim final rules implementing section 2713 of the PHS Act provided the public with an opportunity to comment on the implementation of the preventive services requirements in this provision, and the amendments made in these interim final rules in fact are based on such public comments. Specifically, commenters expressed concerns that HRSA-supported guidelines issued under section 2713(a)(4) that included coverage of contraceptive services could impinge upon the religious freedom of certain religious employers. The flexibility that is afforded under these amendments is being provided to HRSA in order to allow HRSA the discretion to accommodate, in a balanced way, as discussed above, these commenter concerns.

In addition, the Departments have determined that an additional opportunity for public comment would be impractical and contrary to the public interest. The requirement in section 2713(a)(4) that preventive services supported by HRSA be provided without cost-sharing took effect at the beginning of the first plan or policy year beginning on or after September 23, 2010. At that time, however, HRSA had not issued any such guidelines. Under the July 19, 2010 interim final rules, group health plans and insurance issuers do not have to begin covering preventive services supported in HRSA guidelines until the first plan or policy year that begins one year after the guidelines are issued. Thus, while the law requiring coverage of recommended women's preventive health services was enacted on March 23, 2010, and has been in effect since September 23, 2010, no such guidelines have yet been issued, and it will be at least a full year after they are issued before group health plans and issuers will be required to start covering preventive services recommended in the guidelines without cost sharing.

The July 19, 2010 interim final rules indicated that HRSA expected to issue guidelines by August 1, 2011. After considering public comments raising the issue addressed in these amendments, however, the Departments determined that HRSA should be granted the discretion to address the commenter concerns at issue prior to issuing guidelines under section 2713(a)(4). Many college student policy years begin in August and an estimated 1.5 million young adults are estimated to be covered by such policies.[5] Providing an opportunity for public comment as described above would mean that the guidelines could not be issued until after August of 2011. This delay would mean that many students could not benefit from the new prevention coverage without cost-sharing following from the issuance of the guidelines until the 2013–14 school year, as opposed to the 2012–13 school year. Similarly, 2008 data from the Department of Labor indicate that over 4 million Americans have ERISA group health plan coverage that starts in August or September; they too would experience over a year's delay in the receipt of the new benefit if the public comment period delayed the issuance of the guidance for over a month. The Departments have determined that such a delay in implementation of the statutory requirement that women receive vital preventive services without cost-sharing would be contrary to the public interest because it could result in adverse health consequences that may not otherwise have occurred.

While the Departments have determined that, even if the APA were applicable, issuing these regulations in proposed form, so they would not become effective until after public comment, would be contrary to the public interest in the case of these amendments, the Departments are issuing these amendments as interim final rules so as to provide the public with an opportunity for public comment on these amendments.

The APA also generally requires that a final rule be effective no sooner than 30 days after the date of publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause why the effective date should not be delayed, and the agency incorporates a statement of the findings and its reasons in the rule issued.

As indicated above, many college student policy years begin in August. Delaying the effective date of this amendment by 30 days would mean that the HRSA guidelines could not be issued until after August of 2011. This delay would mean many students could not benefit from the new prevention coverage without cost-sharing following from the issuance of the guidelines until the 2013–14 school year, as opposed to the 2012–13 school year. As discussed above, all other participants, beneficiaries and enrollees in plans or policies with a plan or a policy year beginning in the months between August 1 and whenever a final rule would be published should the Departments provide a pre-promulgation opportunity for public comment would face a similar one-year delay in receiving these important health benefits. The Departments have determined that such a delay in implementation of the statutory requirement that women receive vital preventive services without cost-sharing would be impracticable and contrary to the public interest because it could result in adverse health consequences that may not otherwise have occurred. Therefore, the Departments are waiving the 30-day delay in effective date of these amendments.

[5] Department of Health and Human Services, Notice of Proposed Rulemaking on Student Health Insurance Coverage (76 FR 7767, February 22, 2011).

IV. Economic Impact and Paperwork Burden

A. Executive Orders 13563 and 12866—Department of Labor and Department of Health and Human Services

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued interim final regulations implementing PHS Act section 2713 that were published in the **Federal Register** on July 19, 2010 (75 FR 41726). Comments received in response to the interim final regulations raised the issue of imposing on certain religious employers through binding guidelines the requirement to cover contraceptive services that would be in conflict with the religious tenets of the employer. The Departments have determined that it is appropriate to amend the interim final rules to provide HRSA the discretion to exempt from its guidelines group health plans maintained by certain religious employers where contraceptive services are concerned.

2. Anticipated Effects

The Departments expect that this amendment will not result in any additional significant burden or costs to the affected entities.

B. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

C. Paperwork Reduction Act

As stated in the previously issued interim final regulations, this rule is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) because it does not contain a ''collection of information'' as defined in 44 U.S.C. 3502 (11).

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Department of the Treasury

Internal Revenue Service

26 CFR Chapter 1

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2713T is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

* * * * *

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

Subpart C—Other Requirements

■ 2. Section 2590.715–2713 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph

(a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

* * * * *

Department of Health and Human Services

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.130 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(A) In developing the binding health plan coverage guidelines specified in this paragraph (a)(1)(iv), the Health Resources and Services Administration shall be informed by evidence and may establish exemptions from such guidelines with respect to group health plans established or maintained by religious employers and health insurance coverage provided in connection with group health plans established or maintained by religious employers with respect to any requirement to cover contraceptive services under such guidelines.

(B) For purposes of this subsection, a ''religious employer'' is an organization that meets all of the following criteria:

(*1*) The inculcation of religious values is the purpose of the organization.

(*2*) The organization primarily employs persons who share the religious tenets of the organization.

(*3*) The organization serves primarily persons who share the religious tenets of the organization.

(*4*) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

* * * * *

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 28, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this 29th day of July 2011.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

OCIIO–9992–IFC2

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 28, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 28, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–19684 Filed 8–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0717]

RIN 1625–AA00

Safety Zone; Discovery World Private Wedding Firework Displays, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Milwaukee Harbor in Milwaukee, Wisconsin. This zone is intended to restrict vessels from a portion of Milwaukee Harbor during two separate firework displays on July 31, 2011 and August 26, 2011. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with these firework displays.

DATES: This rule is in the CFR on August 3, 2011 through 10:30 p.m. on August 26, 2011. This rule is effective with actual notice for purposes of enforcement at 9:30 p.m. on July 31, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0717 and are available online by going to *http://www.regulations.gov*, inserting USCG–2011–0717 in the Docket ID box, and then clicking ''search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, contact or e-mail BM1 Adam Kraft, U.S. Coast Guard Sector Lake Michigan, at 414–747–7148 or *Adam.D.Kraft@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because waiting for a notice and comment period to run would be impracticable and contrary to the public interest. Notice of this fireworks display was not received in sufficient time for the Coast Guard to solicit public comments before the start of the event. Thus, waiting for a notice and comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect the public from the hazards associated with these maritime fireworks displays.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30-days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run

europa.eu/about-eu/countries/index_en.htm, July 1, 2011.
15. Collin, P., L. Thorell, K. Kaukinen, *et al.*, ''The Safe Threshold for Gluten Contamination in Gluten-Free Products. Can Trace Amounts Be Accepted in the Treatment of Coeliac Disease?'' *Alimentary Pharmacology & Therapeutics*, 19(12):1277–1283, June 2004.
16. Kaukinen, K., P. Collin, K. Holm, *et al.*, ''Wheat Starch-Containing Gluten-Free Flour Products in the Treatment of Coeliac Disease and Dermatitis Herpetiformis: A Long-Term Follow-up Study,'' *Scandinavian Journal of Gastroenterology*, 34(2):163–169, January 1999.
17. Peräaho, M., K. Kaukinen, K. Paasikivi, *et al.*, ''Wheat-Starch-Based Gluten-Free Products in the Treatment of Newly Detected Coeliac Disease: Prospective and Randomized Study,'' Alimentary *Pharmacology & Therapeutics*, 17(4):587–594, February 2003.
18. Hischenhuber, C., R. Crevel, B. Jarry, *et al.*, ''Review Article: Safe Amounts of Gluten for Patients With Wheat Allergy or Coeliac Disease,'' *Alimentary Pharmacological & Therapeutics*, 23(5):559–575, March 2006.
19. Gibert, A., M. Espadaler, M. Canela, et al., ''Consumption of Gluten-Free Products: Should the Threshold Value for Trace Amounts of Gluten Be at 20, 100 or 200 p.p.m.?'' *European Journal of Gastroenterology & Hepatology*, 18(11):1187–1195, 2006.
20. Akobeng, A. and A. Thomas, ''Systematic Review: Tolerable Amount of Gluten for People With Celiac Disease,'' *Alimentary Pharmacology & Therapeutics*, 27(11):1044–1052, June 2008.

Dated: July 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19620 Filed 8–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40 and 49

[REG–112841–10]

RIN 1545–BJ40

Indoor Tanning Services; Cosmetic Services Excise Taxes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of public hearing on proposed rulemaking providing guidance on the indoor tanning services excise tax imposed by the Patient Protection and Affordable Care Act. These regulations affect users and providers of indoor tanning services.

DATES: The public hearing is being held on Tuesday, October 11, 2011, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the public hearing by September 28, 2011.

ADDRESSES: The public hearing is being held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building.

Mail outlines to CC:PA:LPD:PR (REG–112841–10), Room 5205, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–112841–10), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–112841–10).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Michael H. Beker at (202) 622–3130; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing Regina Johnson at (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–112841–10) that was published in the **Federal Register** on Tuesday, June 15, 2010 (75 FR 33740). The notice also announced that a hearing will be scheduled if requested by the public in writing by September 13, 2010.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline has passed, persons who have submitted written comments and wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (a signed original and four copies) by September 28, 2010.

The IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available free of charge, at the hearing. Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

LaNita Van Dyke,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2011–19597 Filed 8–2–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–120391–10]

RIN 1545–BJ58

Requirements for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: Elsewhere in this issue of the **Federal Register**, the IRS is issuing an amendment to temporary regulations published July 19, 2010, under the provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act) relating to coverage of preventive services without any participant cost sharing. The IRS is issuing the temporary regulations at the same time that the Employee Benefits Security Administration of the U.S. Department of Labor and the Center for Consumer Information & Insurance Oversight of the U.S. Department of Health and Human Services are issuing a substantially similar amendment to interim final regulations published July 19, 2010 with respect to group health plans and health insurance coverage offered in connection with a group health plan under the Employee Retirement Income Security Act of 1974 and the Public Health Service Act. The temporary regulations provide guidance to employers, group health plans, and health insurance issuers providing group health insurance coverage. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by October 3, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–120391–10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:PA:LPD:PR (REG–120391–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–120391–10).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Karen Levin at 202–622–6080; concerning submissions of comments, Treena Garrett at 202–622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

The temporary regulations published elsewhere in this issue of the **Federal Register** amend § 54.9815–2713T of the Miscellaneous Excise Tax Regulations. The proposed and temporary regulations are being published as part of a joint rulemaking with the Department of Labor and the Department of Health and Human Services (the joint rulemaking). The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information requirement on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are specifically requested on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Karen Levin, Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), IRS. The proposed regulations, as well as the temporary regulations, have been developed in coordination with personnel from the U.S. Department of Labor and the U.S. Department of Health and Human Services.

List of Subjects in 26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54, as proposed to be amended on July 19, 2010, at 75 FR 41787. is further proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 54.9815–2713, as proposed to be added at 75 FR 41788, July 19, 2010, is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(iv) [The text of proposed § 54.9815–2713(a)(1)(iv) is the same as the text of § 54.9815–2713T(a)(1)(iv) published elsewhere in this issue of the **Federal Register**].

* * * * *

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–19685 Filed 8–1–11; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2011–0108; FRL–8878–3]

RIN 2070–AB27

Tris carbamoyl triazine; Proposed Modification of Significant New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under section 5(a)(2) of the Toxic Substances Control Act (TSCA), EPA is proposing to amend the significant new use rule (SNUR) for the chemical substance identified generically as tris carbamoyl triazine, which was the subject to premanufacture notice (PMN) P–95–1098. This action would amend the SNUR to allow certain uses without requiring a significant new use notice (SNUN), and would extend SNUN requirements to certain additional uses. EPA is proposing this amendment based on review of new toxicity test data.

DATES: Comments must be received on or before September 2, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2011–0108, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. *Attention:* Docket ID Number EPA–HQ–OPPT–2011–0108. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2011–0108. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information

TABLE I—Continued

Year	Limit	
	Auto. proj. cost limit (Col. 1)	Prior notice proj. cost limit (Col. 2)
2003 ..	7,600,000	21,200,000
2004 ..	7,800,000	21,600,000
2005 ..	8,000,000	22,000,000
2006 ..	9,600,000	27,400,000
2007 ..	9,900,000	28,200,000
2008 ..	10,200,000	29,000,000
2009 ..	10,400,000	29,600,000
2010 ..	10,500,000	29,900,000
2011 ..	10,600,000	30,200,000
2012 ..	10,800,000	30,800,000

* * * * *

■ 3. Table II in § 157.215(a)(5) is revised to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000
1997	4,400,000
1998	4,500,000
1999	4,550,000
2000	4,650,000
2001	4,750,000
2002	4,850,000
2003	4,900,000
2004	5,000,000
2005	5,100,000
2006	5,250,000
2007	5,400,000
2008	5,550,000
2009	5,600,000
2010	5,700,000
2011	5,750,000
2012	5,850,000

* * * * *

[FR Doc. 2012–3488 Filed 2–14–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9578]

RIN 1545–BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9992–F]

RIN 0938–AQ74

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These regulations finalize, without change, interim final regulations authorizing the exemption of group health plans and group health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under provisions of the Patient Protection and Affordable Care Act.

DATES: *Effective date.* These final regulations are effective on April 16, 2012.

Applicability dates. These final regulations generally apply to group health plans and group health insurance issuers on April 16, 2012.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Robert Imes, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the CMS Web site (*http://cciio.cms.gov*), and on health reform can be found at *http://www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010 (collectively, the Affordable Care Act). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage provide benefits for certain preventive health services without the imposition of cost sharing. These preventive health services include, with respect to women, preventive care and screening provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) that were issued on August 1, 2011 (HRSA Guidelines).[1] As relevant here, the HRSA Guidelines require coverage, without cost sharing, for ''[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity,'' as prescribed by a provider. Except as discussed below, non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, in plan years (or,

[1] The HRSA Guidelines can be found at: *http://www.hrsa.gov/womensguidelines.*

in the individual market, policy years) beginning on or after August 1, 2012.[2] These guidelines were based on recommendations of the independent Institute of Medicine, which undertook a review of the evidence on women's preventive services.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published interim final regulations implementing PHS Act section 2713 on July 19, 2010 (75 FR 41726). In the preamble to the interim final regulations, the Departments explained that HRSA was developing guidelines related to preventive care and screening for women that would be covered without cost sharing pursuant to PHS Act section 2713(a)(4), and that these guidelines were expected to be issued no later than August 1, 2011. Although comments on the anticipated guidelines were not requested in the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be covered without cost sharing. Some commenters, including some religiously-affiliated employers, recommended that these guidelines include contraceptive services among the recommended women's preventive services and that the attendant coverage requirement apply to all group health plans and health insurance issuers. Other commenters, however, recommended that group health plans sponsored by religiously-affiliated employers be allowed to exclude contraceptive services from coverage under their plans if the employers deem such services contrary to their religious tenets, noting that some group health plans sponsored by organizations with a religious objection to contraceptives currently contain such exclusions for that reason.

In response to these comments, the Departments amended the interim final regulations to provide HRSA with discretion to establish an exemption for group health plans established or maintained by certain religious employers (and any group health insurance coverage provided in connection with such plans) with respect to any requirement to cover contraceptive services that they would otherwise be required to cover without cost sharing consistent with the HRSA Guidelines. The amended interim final regulations were issued and effective on August 1, 2011.[3] The amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. In the HRSA Guidelines, HRSA exercised its discretion under the amended interim final regulations such that group health plans established and maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) are not required to cover contraceptive services.

In the preamble to the amended interim final regulations, the Departments explained that it was appropriate that HRSA take into account the religious beliefs of certain religious employers where coverage of contraceptive services is concerned. The Departments noted that a religious exemption is consistent with the policies in some States that currently both require contraceptive services coverage under State law and provide for some type of religious exemption from their contraceptive services coverage requirement. Comments were requested on the amended interim final regulations, specifically with respect to the definition of religious employer, as well as alternative definitions.

II. Overview of the Public Comments on the Amended Interim Final Regulations

The Departments received over 200,000 responses to the request for comments on the amended interim final regulations. Commenters included concerned citizens, civil rights organizations, consumer groups, health care providers, health insurance issuers, sponsors of group health plans, religiously-affiliated charities, religiously-affiliated educational institutions, religiously-affiliated health care organizations, other religiously-affiliated organizations, secular organizations, sponsors of group health plans, women's religious orders, and women's rights organizations.

Some commenters recommended that the exemption for the group health plans of a limited group of religious organizations as formulated in the amended interim final regulations be maintained. Other commenters urged that the definition of religious employer be broadened so that more sponsors of group health plans would qualify for the exemption. Others urged that the exemption be rescinded in its entirety. The Departments summarize below the major issues raised in the comments that were received.

Some commenters supported the inclusion of contraceptive services in the HRSA Guidelines and urged that the religious employer exemption be rescinded in its entirety due to the importance of extending these benefits to as many women as possible. For example, one provider association commented that all group health plans and group health insurance issuers should offer the same benefits to plan participants, without a religious exemption for some plans, and that religious beliefs are more appropriately taken into account by individuals when making personal health care decisions. Others urged that the exemption be eliminated because making contraceptive services available to all women would satisfy a basic health care need and would significantly reduce long-term health care costs associated with unplanned pregnancies.

Some of the commenters supporting the elimination of the exemption argued that section 2713 of the PHS Act does not provide any explicit basis for exempting a subset of group health plans. One commenter asserted that Congress's incorporation of section 2713 of the PHS Act into ERISA and the Code indicates its intent to require coverage of recommended preventive services under section 2713 of the PHS Act in the broadest spectrum of group health plans possible.

Many commenters that opposed the exemption asked that, at a minimum, the Departments not expand the definition of religious employer. Alternatively, they asked that, if the Departments decided to base the relevant portion of the definition of religious employer on a Code section other than section 6033, the other portions of the definition of religious employer be retained to limit the exemption largely to houses of worship.

Some commenters urged the Departments not to modify the definition of religious employer. For example, some commenters asserted that the exemption is appropriately

[2] The interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (or, in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation or guideline is issued. 26 CFR 54.9815–2713T(b)(1); 29 CFR 2590.715–2713(b)(1); 45 CFR 147.130(b)(1).

[3] The amendment to the interim final regulations was published on August 3, 2011, at 76 FR 46621.

targeted at houses of worship, rather than a larger set of religiously-affiliated organizations. Others argued that, while the exemption addresses legitimate religious concerns, its scope is already broader than necessary and should not be expanded.

Commenters opposing any exemption stated that, if the exemption were to be retained, clear notice should be provided to the affected plan participants that their group health plans do not include benefits for contraceptive services. In addition, they urged the Departments to monitor plans to ensure that the exemption is not claimed more broadly than permitted.

On the other hand, a number of comments asserted that the religious employer exemption is too narrow. These commenters included some religiously-affiliated educational institutions, health care organizations, and charities. Some of these commenters expressed concern that the exemption for religious employers will not allow them to continue their current exclusion of contraceptive services from coverage under their group health plans. Others expressed concerns about paying for such services and stated that doing so would be contrary to their religious beliefs.

Commenters also claimed that Federal laws, including the Affordable Care Act, have provided for conscience clauses and religious exemptions broader than that provided for in the amended interim final regulations. Some commenters asserted that the narrower scope of the exemption raises concerns under the First Amendment and the Religious Freedom Restoration Act.

Other commenters, however, disputed claims that the contraceptive coverage requirement infringes on rights protected by the First Amendment or the Religious Freedom Restoration Act. These commenters noted that the requirement is neutral and generally applicable. They also explained that the requirement does not substantially burden religious exercise and, in any event, serves compelling governmental interests and is the least restrictive means to achieve those interests.

Some religiously-affiliated employers warned that, if the definition of religious employer is not broadened, they could cease to offer health coverage to their employees in order to avoid having to offer coverage to which they object on religious grounds.

Commenters supporting a broadening of the definition of religious employer proposed a number of options, generally intended to expand the scope of the exemption to include religiously-affiliated educational institutions, health care organizations, and charities. In some instances, in place of the definition that was adopted in the amended interim final regulations, commenters suggested other State insurance law definitions of religious employer. In other instances, commenters referenced alternative standards, such as tying the exemption to the definition of ''church plan'' under section 414(e) of the Code or to status as a nonprofit organization under section 501(c)(3) of the Code.

III. Overview of the Final Regulations

In response to these comments, the Departments carefully considered whether to eliminate the religious employer exemption or to adopt an alternative definition of religious employer, including whether the exemption should be extended to a broader set of religiously-affiliated sponsors of group health plans and group health insurance coverage. For the reasons discussed below, the Departments are adopting the definition in the amended interim final regulations for purposes of these final regulations while also creating a temporary enforcement safe harbor, discussed below. During the temporary enforcement safe harbor, the Departments plan to develop and propose changes to these final regulations that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services as also discussed below.

PHS Act section 2713 reflects a determination by Congress that coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers without cost sharing is necessary to achieve basic health care coverage for more Americans. Individuals are more likely to use preventive services if they do not have to satisfy cost sharing requirements (such as a copayment, coinsurance, or a deductible). Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive treatment earlier.[4] Further, Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women are covered adequately by non-grandfathered group health plans and group health insurance coverage, recognized that women have unique health care needs and burdens. Such needs include contraceptive services.[5]

As documented in a report of the Institute of Medicine, ''Clinical Preventive Services for Women, Closing the Gaps,'' women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may not be as motivated to discontinue behaviors that pose pregnancy-related risks (e.g., smoking, consumption of alcohol). Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies compared with pregnancies that were planned.[6] Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (e.g., treatment of menstrual disorders, acne, and pelvic pain).[7]

In addition, there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 15 to17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs such as employee absence and reduced productivity.[8] In fact, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting

[4] Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps,* Wash., DC: Nat'l Acad. Press, 2011, at p. 16.

[5] Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps,* Wash. DC: Nat'l Acad. Press, 2011, at p. 9; *see also* Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Pol'y Rev.* 10 (2011), available at *http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.html.*

[6] Gipson, J.D., et al., The Effects of Unintended Pregnancy on Infant, Child and Parental Health: A Review of the Literature, *Studies on Family Planning,* 2008, 39(1):18–38.

[7] Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps,* Wash., DC: Nat'l Acad. Press, 2011, at p. 107.

[8] Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p. 11 citing Bonoan, R + Gonen, JS, ''Promoting Healthy Pregnancies: Counseling and Contraception as the First Step'', Washington Business Group on Health, Family Health in Brief, Issue No. 3. August 2000; *see also* Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies without Cost Sharing, 14 *Guttmacher Pol'y Rev.* 10 (2011); Mavranezouli, I., Health Economics of Contraception, 23 *Best Practice & Res. Clinical Obstetrics & Gynaecology* 187–198 (2009); Trussell, J., et al., Cost Effectiveness of Contraceptives in the United States, 79 *Contraception* 5–14 (2009); Trussell, J., The Cost of Unintended Pregnancy in the United States, 75 *Contraception* 168–170 (2007).

health care cost increase.[9] Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives.[10] A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives.[11]

Furthermore, in directing non-grandfathered group health plans and health insurance issuers to cover preventive services and screenings for women described in HRSA-supported guidelines without cost sharing, Congress determined that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity places women in the workforce at a disadvantage compared to their male co-workers. Researchers have shown that access to contraception improves the social and economic status of women.[12] Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force. Research also shows that cost sharing can be a significant barrier to effective contraception.[13] As the Institute of Medicine noted, owing to reproductive and sex-specific conditions, women use preventive services more than men, generating significant out-of-pocket expenses for women.[14] The Departments aim to reduce these disparities by providing women broad access to preventive services, including contraceptive services.

The religious employer exemption in the final regulations does not undermine the overall benefits described above. A group health plan (and health insurance coverage provided in connection with such a plan) qualifies for the exemption if, among other qualifications, the plan is established and maintained by an employer that primarily employs persons who share the religious tenets of the organization. As such, the employees of employers availing themselves of the exemption would be less likely to use contraceptives even if contraceptives were covered under their health plans.

A broader exemption, as urged by some commenters, would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives, which would undermine the benefits described above. Employers that do not primarily employ employees who share the religious tenets of the organization are more likely to employ individuals who have no religious objection to the use of contraceptive services and therefore are more likely to use contraceptives. Including these employers within the scope of the exemption would subject their employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care.

The Departments note that this religious exemption is intended solely for purposes of the contraceptive services coverage requirement pursuant to PHS Act section 2713 and the companion provisions of ERISA and the Code.

The Departments also note that some group health plans sponsored by employers that do not satisfy the definition of religious employer in these final regulations may be grandfathered health plans [15] and thus are not subject to any of the preventive services coverage requirements of section 2713 of the PHS Act, including the contraceptive coverage requirement.

With respect to certain non-exempted, non-profit organizations with religious objections to covering contraceptive services whose group health plans are not grandfathered health plans, guidance is being issued contemporaneous with these final regulations that provides a one-year safe harbor from enforcement by the Departments.

Before the end of the temporary enforcement safe harbor, the Departments will work with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing with respect to non-exempted, non-profit religious organizations with religious objections to such coverage. Specifically, the Departments plan to initiate a rulemaking to require issuers to offer insurance without contraception coverage to such an employer (or plan sponsor) and simultaneously to offer contraceptive coverage directly to the employer's plan participants (and their beneficiaries) who desire it, with no cost-sharing. Under this approach, the Departments will also require that, in this circumstance, there be no charge for the contraceptive coverage. Actuaries and experts have found that coverage of contraceptives is at least cost neutral when taking into account all costs and benefits in the health plan.[16] The Departments intend to develop policies to achieve the same goals for self-insured group health plans sponsored by non-exempted, non-profit religious organizations with religious objections to contraceptive coverage.

A future rulemaking would be informed by the existing practices of some issuers and religious organizations in the 28 States where contraception coverage requirements already exist, including Hawaii. There, State health insurance law requires issuers to offer plan participants in group health plans sponsored by religious employers that are exempt from the State contraception coverage requirement the option to purchase this coverage in a way that religious employers are not obligated to fund it. It is our understanding that, in practice, rather than charging employees a separate fee, some issuers in Hawaii offer this coverage to plan participants at no charge. The Departments will work with stakeholders to propose and

[9] Dailard, C., Special Analysis: The Cost of Contraceptive Insurance Coverage, *Guttmacher Rep. on Public Pol'y* (March 2003).

[10] Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

[11] Claxton, G., et al., *Employer Health Benefits: 2010 Annual Survey,* Menlo Park, Cal.: Kaiser Family Found. and Chi., Ill.: Health Research & Educ. Trust, 2010.

[12] Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p.6, citing Goldin C and Katz L, Career and marriage in the age of the pill, *American Economic Review,* 2000, 90(2):461–465; Goldin C and Katz LF, The power of the pill: oral contraceptives and women's career and marriage decisions, *Journal of Political Economy,* 2002, 110(4):730–770; and Bailey MJ, More power to the pill: the impact of contraceptive freedom on women's life cycle labor supply, *Quarterly Journal of Economics,* 2006, 121(1):289–320.

[13] Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, 76 *Contraception* 360 (2007).

[14] Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps,* Wash., DC: Nat'l Acad. Press, 2011, p.19.

[15] See section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815–1251T; 29 CFR 2590.715–1251; 45 CFR 147.140.

[16] Bertko, John, F.S.A., M.A.A.A., Director of Special Initiatives and Pricing in the Center for Consumer Information and Insurance Oversight at the Centers for Medicare and Medicaid Services, Glied, Sherry, Ph.D., Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services (ASPE/HHS), Miller, Erin, MPH, (ASPE/HHS), Wilson, Lee, (ASPE/HHS), Simmons, Adelle, (ASPE/HHS), ''The Cost of Covering Contraceptives through Health Insurance,'' (9 February 2012), available at: *http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml.*

finalize this policy before the end of the temporary enforcement safe harbor.

Nothing in these final regulations precludes employers or others from expressing their opposition, if any, to the use of contraceptives, requires anyone to use contraceptives, or requires health care providers to prescribe contraceptives if doing so is against their religious beliefs. These final regulations do not undermine the important protections that exist under conscience clauses and other religious exemptions in other areas of Federal law. Conscience protections will continue to be respected and strongly enforced.

This approach is consistent with the First Amendment and Religious Freedom Restoration Act. The Supreme Court has held that the First Amendment right to free exercise of religion is not violated by a law that is not specifically targeted at religiously motivated conduct and that applies equally to conduct without regard to whether it is religiously motivated—a so-called neutral law of general applicability. The contraceptive coverage requirement is generally applicable and designed to serve the compelling public health and gender equity goals described above, and is in no way specially targeted at religion or religious practices. Likewise, this approach complies with the Religious Freedom Restoration Act, which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest.

III. Economic Impact and Paperwork Burden

A. Executive Orders 13563 and 12866—Department of Labor and Department of Health and Human Services

Executive Orders 13563 and 12866, among other things, direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13563 also states that where ''appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.'' These final regulations have been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, these final regulations have been reviewed by the Office of Management and Budget.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued amended interim final regulations authorizing an exemption for group health plans and health insurance coverage sponsored by certain religious employers from certain coverage requirements under PHS Act section 2713 (76 FR 46621, August 3, 2011). The Departments have determined that it is appropriate to finalize, without change, these amended interim final regulations authorizing the exemption of group health plans and health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under the Patient Protection and Affordable Care Act.

2. Anticipated Effects

The Departments expect that these final regulations will not result in any additional significant burden or costs to the affected entities.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these final regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

C. Paperwork Reduction Act

These final regulations are not subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) because they do not contain a ''collection of information'' as defined in 44 U.S.C. 3502(11).

IV. Statutory Authority

The Department of the Treasury final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9815–2713 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–2713 also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9815–2713T is amended in paragraph (a)(1)(iii) by removing ''; and'' and adding a period in its place, and by removing paragraph (a)(1)(iv).

■ **Par. 3.** Section 54.9815–2713 is added to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* [Reserved]

(i) [Reserved]

(ii) [Reserved]

(iii) [Reserved]

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of § 54.9815–2713T, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

(2) *Office visits.* [Reserved]

(3) *Out-of-network providers.* [Reserved]

(4) *Reasonable medical management.* [Reserved]

(5) *Services not described.* [Reserved]

(b) *Timing.* [Reserved]

(c) *Recommendations not current.* [Reserved]

(d) *Effective/applicability date.* April 16, 2012.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

■ 2. Accordingly, the amendment to the interim final rule with comment period amending 29 CFR 2590.715–2713(a)(1)(iv) which was published in the **Federal Register** at 76 FR 46621–46626 on August 3, 2011, is adopted as a final rule without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Accordingly, the amendment to the interim final rule with comment period amending 45 CFR 147.130(a)(1)(iv) which was published in the **Federal Register** at 76 FR 46621–46626 on August 3, 2011, is adopted as a final rule without change.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: February 10, 2012.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this 10th day, of February 2012.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: February 10, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 10, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–3547 Filed 2–10–12; 3:45 pm]

BILLING CODE 4120–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2012. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective March 1, 2012.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for March 2012.[1]

The March 2012 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for February 2012, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

SUMMARY: This document contains a correction to a notice of proposed rulemaking (REG–132554–08) that was published in the **Federal Register** on Tuesday, October 19, 2010 (75 FR 64197) providing guidance relating to certain provisions of the Internal Revenue Code that apply to hybrid defined benefit pension plans.

FOR FURTHER INFORMATION CONTACT: Neil S. Sandhu, Lauson C. Green, or Linda S. F. Marshall at (202) 622–6090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 411 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG–132554–08) contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–132554–08), which was the subject of FR Doc. 2010–25942, is corrected as follows:

§ 1.411(b)(5)–1 [Corrected]

On page 64214, column 3, § 1.411(b)(5)–1(e)(2)(iii)(A), line 19, the language "change the rate of interest crediting" is corrected to read "change the interest crediting rate".

Guy R. Traynor,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedure and Administration.

[FR Doc. 2010–32538 Filed 12–27–10; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

Request for Information Regarding Value-Based Insurance Design in Connection With Preventive Care Benefits

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This document contains a request for information on how group health plans and health insurance issuers can employ value-based insurance design in the coverage of recommended preventive services.

DATES: Comments are due on or before February 28, 2011.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by VBID, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: E–OHPSCA–VBID.EBSA@dol.gov.*
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* VBID.

Comments received by the Department of Labor will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code HHS–OS–2010–002. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.
- *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: HHS–OS–2010–002, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: HHS–OS–2010–002, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.
- *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the following address: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: HHS–OS–2010–002, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of

filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Internal Revenue Service. Comments to the IRS, identified by REG–120391–10 VBID, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* CC:PA:LPD:PR (REG–120391–10 VBID), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–120391–10 VBID), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in Room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Lisa Campbell, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492–4100.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (*http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp*) and the Office of Consumer Information & Insurance Oversight (OCIIO) Web site (*http://www.hhs.gov/OCIIO*).

SUPPLEMENTARY INFORMATION:

I. Background

Section 1001 of the Patient Protection and Affordable Care Act (the Affordable Care Act) added a new section 2713 to the Public Health Service Act (the PHS Act), relating to preventive care. The Affordable Care Act also added a new section 715(a)(1) to the Employee Retirement Income Security (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) incorporating the provisions of part A of title XXVII of the PHS Act (including PHS Act section 2713) into ERISA and the Code, making section 2713 applicable to group health plans and health insurance coverage in connection with group health plans. The Departments of the Treasury, Labor, and Health and Human Services (the Departments) published interim final regulations implementing the provisions of PHS Act section 2713 on July 19, 2010, at 75 FR 41726.

Section 2713 of the PHS Act and the Departments' implementing regulations apply to group health plans and health insurance issuers offering group or individual health insurance coverage that is not grandfathered.[1] These provisions require such plans and issuers to provide coverage for recommended preventive services, without imposing cost-sharing requirements.[2] The complete list of items and services that are required to be covered under these interim final regulations can be found at *http://www.HealthCare.gov/center/regulations/prevention.html.*

The interim final regulations clarify that, with respect to a plan or health insurance coverage that has a network of providers, a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. Such a plan or issuer may also impose cost-sharing requirements for recommended preventive services delivered by an out-of-network provider.

The interim final regulations also provide that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines for coverage of specific items and services where cost sharing must be waived. Thus, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline.

The preamble to the interim final regulations also invited comments on value-based insurance designs (VBID). In general, VBID includes the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. The preamble stated:

> The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services. These interim final regulations, for example, permit plans and issuers to implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. The Departments are developing additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits. The Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

In response to the solicitation of comments, the Departments received about 25 comment letters regarding VBID. Many commenters cited the importance of using VBID to help control rising health care costs and promote better health care outcomes. A number of other commenters raised

[1] For information on whether a particular group health plan or health insurance coverage is a grandfathered plan, *see* Affordable Care Act section 1251 and the Departments' implementing regulations at 75 FR 34538 (as amended by 75 FR 70114).

[2] In general, the recommended preventive services are: (1) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved; (2) immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and (4) with respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force).

concerns about VBID becoming a barrier to access to services. Some also questioned how value would be assessed and whether that assessment would include measures such as quality and effectiveness, not solely measures of cost.

The Departments remain interested in promoting high-value, clinically effective, evidence-based preventive care. (Outside the context of preventive care, the coverage requirements and cost-sharing prohibition of PHS Act section 2713 are not applicable.) The Departments are issuing the fifth in a series of Affordable Care Act Implementation Frequently Asked Questions (FAQs), which identifies certain health plan design elements that are considered to comply with PHS Act section 2713. To inform future guidance, this RFI solicits additional information on specific examples and best practices of VBID for recommended preventive services, as well as data used to support and inform VBID benefit design, measurement, and evaluation in the context of recommended preventive services.

II. Solicitation of Comments

A. Comments Regarding Regulatory Guidance

This RFI requests comments generally on VBID in the context of recommended preventive services, as well as specifically on the following questions:

1. What specific plan design tools do plans and issuers currently use to incentivize patient behavior, and which tools are perceived as most effective (for example, specific network design features, targeted cost-sharing mechanisms)? How is effective defined?

2. Do these tools apply to all types of benefits for preventive care, or are they targeted towards specific types of conditions (for example, diabetes) or preventive services treatments (for example, colonoscopies, scans)?

3. What considerations do plans and issuers give to what constitutes a high-value or low-value treatment setting, provider, or delivery mechanism? What is the threshold of acceptable value? What factors impact how this threshold varies between services? What data are used? How is quality measured as part of this analysis? What time frame is used for assessing value? Are the data readily available from public sources, or are they internal and/or considered proprietary?

4. What data do plans and issuers use to determine appropriate incentive models and/or amounts in steering patients towards high-value and/or away from low-value mechanisms for delivery of a given recommended preventive service?

5. How often do plans and issuers re-evaluate data and plan design features? What is the process for re-evaluation? Specifically:

a. How is the impact of VBID on patient utilization monitored?

b. How is the impact of VBID on patient out-of-pocket costs monitored?

c. How is the impact of VBID on health plan costs monitored?

d. What factors are considered in evaluating effectiveness (for example, cost, quality, utilization)?

6. Are there particular instances in which a plan or issuer has decided not to adopt or continue a particular VBID method? If so, what factors did they consider in reaching that decision?

7. What are the criteria for adopting VBID for new or additional preventive care benefits or treatments?

8. Do plans or issuers currently implement VBIDs that have different cost-sharing requirements for the same service based on population characteristics (for example, high vs. low risk populations based on evidence)?

9. What would be the data requirements and other administrative costs associated with implementing VBIDs based on population characteristics across a wide range of preventive services?

10. What mechanisms and/or safety valves, if any, do plans and issuers put in place or what data are used to ensure that patients with particular co-morbidities or special circumstances, such as risk factors or the accessibility of services, receive the medically appropriate level of care? For example, to the extent a low-cost alternative treatment is reasonable for some or the majority of patients, what happens to the minority of patients for whom a higher-cost service may be the only medically appropriate one?

11. What other factors, such as ensuring adequate access to preventive services, are considered as part of a plan or issuer's VBID strategy?

12. How are consumers informed about VBID features in their health coverage?

13. How are prescribing physicians/other network providers informed of VBID features and/or encouraged to steer patients to value based services and settings?

14. What consumer protections, if any, need to be in place to ensure adequate access to preventive care without cost sharing, as required under PHS Act section 2713?

B. Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 (EO 12866) requires an assessment of the anticipated costs and benefits of a significant rulemaking action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, a determination must be made whether implementation of this rule will be economically significant. A rule that has an annual effect on the economy of $100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act (RFA) may require the preparation of an analysis of the impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting, recordkeeping, and other compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities. For this purpose, the Departments consider a small entity to be an employee benefit plan with fewer than 100 participants.

The Paperwork Reduction Act (PRA) requires an estimate of how many respondents will be required to comply with any "collection of information" requirements contained in regulations and how much time and cost will be incurred as a result. A collection of information includes recordkeeping, reporting to governmental agencies, and third-party disclosures.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

1. What costs and benefits are associated with expanded use of VBID methods? How do costs and benefits vary among different types of preventive screenings, lifestyle interventions, medications, immunizations, and diagnostic tests?

2. What policies, procedures, practices and disclosures of group

health plans and health insurance issuers would be impacted by expanded use of VBID methods? What direct or indirect costs and benefits would result? Which stakeholders will be impacted by such benefits and costs?

3. What impact would expanded use of VBID methods have on small employers or small plans? Are there unique costs or benefits for small plans? What special considerations, if any, should the Departments take into account for small employers or small plans?

Signed at Washington, DC on December 20, 2010.

Nancy J. Marks,

Division Counsel/Associate Chief Counsel, Tax Exempt and Government Entities, Internal Revenue Service, Department of the Treasury.

Signed at Washington, DC on December 21, 2010.

George H. Bostick

Benefits Tax Counsel, Department of the Treasury.

Signed at Washington, DC on December 16, 2010.

Phyllis C. Borzi

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Dated: December 21, 2010.

Jay Angoff

Director, Office of Consumer Information and Insurance Oversight.

[FR Doc. 2010–32612 Filed 12–27–10; 8:45 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 182

[DOD–2009–OS–0038; RIN 0790–AI54]

Defense Support of Civilian Law Enforcement Agencies

AGENCY: Department of Defense.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements 32 CFR part 185 and legislation concerning restriction on direct participation by DoD personnel. It provides specific policy direction and assigns responsibilities with respect to DoD support provided to Federal, State, and local civilian law enforcement efforts, including responses to civil disturbances.

DATES: Comments must be received by February 28, 2011.

ADDRESSES: You may submit comments, identified by docket number and or RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, OSD Mailroom 3C843, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Tom LaCrosse, 703–697–5822.

SUPPLEMENTARY INFORMATION:

Executive Order 12866, "Regulatory Planning and Review"

It has been certified that 32 CFR part 182 does not:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribunal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Section 202, Public Law 104–4, "Unfunded Mandates Reform Act"

It has been certified that 32 CFR part 182 does not contain a Federal mandate that may result in the expenditure by State, local, and tribunal governments, in aggregate, or by the private sector, of $100 million or more in any 1 year.

Public Law 96–354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been certified that 32 CFR part 182 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule establishes procedures and assigns responsibilities within DoD for assisting civilian law enforcement agencies, therefore, it is not expected that small entities will be affected because there will be no economically significant regulatory requirements placed upon them.

Public Law 96–511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 182 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, "Federalism"

It has been certified that 32 CFR part 182 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 182

Armed forces, Law enforcement.

Accordingly, 32 CFR part 182 is proposed to be added to read as follows:

PART 182—DEFENSE SUPPORT OF CIVILIAN LAW ENFORCEMENT AGENCIES

Sec.

Authority: Legal authorities include title 10 U.S.C. 113, 331–334, 371–382, 2576, and 2667; title 14 U.S.C. 141; title 16 U.S.C. 23, 78, 593, and 1861; title 18 U.S.C. 112, 351, 831, 1116, 1385, and 1751; title 22 U.S.C. 408, 461–462; title 25 U.S.C. 180; title 31 U.S.C. 1535; title 42 U.S.C. 97, 1989, and 5121–5207 (Stafford Act); title 50 U.S.C. 1621–1622; Public Law 94–524, and Executive Order 12656.

§ 182.1. Purpose.

This part implements 32 CFR part 185 and title 10, United States Code (U.S.C.) 375 concerning restriction on direct participation by DoD personnel. It provides specific policy direction and assigns responsibilities with respect to DoD support provided to Federal, State, and local civilian law enforcement efforts, including responses to civil disturbances.

§ 182.2. Applicability and scope.

This part:

(a) Applies to the Office of the Secretary of Defense (OSD), the Military

Women's Preventive Services: Required Health Plan Coverage Guidelines

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Women's Preventive Services: Required Health Plan Coverage Guidelines Supported by the Health Resources and Services Administration

Under the Affordable Care Act, women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services – is covered with no cost sharing for new health plans. However, the law recognizes and HHS understands the need to take into account the unique health needs of women throughout their lifespan.

The HRSA-supported health plan coverage guidelines, developed by the Institute of Medicine (IOM), will help ensure that women receive a comprehensive set of preventive services without having to pay a co-payment, co-insurance or a deductible. HHS commissioned an IOM study to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. HRSA is supporting the IOM's recommendations on preventive services that address health needs specific to women and fill gaps in existing guidelines.

Health Resources and Services Administration Supported Women's Preventive Services: Required Health Plan Coverage Guidelines

Non-grandfathered plans and issuers are required to provide coverage without cost sharing consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Type of Preventive Service	HHS Guideline for Health Insurance Coverage	Frequency
Well-woman visits.	Well-woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally	Annual, although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending

Comment on the Guidelines

Share your comments on the Guidelines by e-mail to womensguidelines@hrsa.gov.

Learn More

Women's Preventive Services: Required Health Plan Coverage Guidelines fact sheet

Clinical Preventive Services for Women: Closing the Gaps Institute of Medicine report

Recommended Preventive Services under the Affordable Care Act

	appropriate, including preconception and prenatal care. This well-woman visit should, where appropriate, include other preventive services listed in this set of guidelines, as well as others referenced in section 2713.	on a woman's health status, health needs, and other risk factors.* (see note)
Screening for gestational diabetes.	Screening for gestational diabetes.	In pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing.	High-risk human papillomavirus DNA testing in women with normal cytology results.	Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections.	Counseling on sexually transmitted infections for all sexually active women.	Annual.
Counseling and screening for human immune-deficiency virus.	Counseling and screening for human immune-deficiency virus infection for all sexually active women.	Annual.
Contraceptive methods and counseling. ** (see note)	All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.	As prescribed.
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment.	In conjunction with each birth.
Screening and counseling for interpersonal and domestic violence.	Screening and counseling for interpersonal and domestic violence.	Annual.

** Refer to recommendations listed in the July 2011 IOM report entitled Clinical Preventive Services for Women: Closing the Gaps concerning individual preventive services that may be obtained during a well-woman preventive service visit.*

*** Group health plans sponsored by certain religious employers, and group health insurance coverage in connection with such plans, are exempt from the requirement to cover contraceptive services. A religious employer is one that: (1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization under Internal Revenue Code section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii). 45 C.F.R. §147.130(a)(1)(iv)(B). See the Federal Register Notice:* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (PDF - 201 KB)

DEPARTMENT OF HEALTH & HUMAN SERVICES Washington, DC 20201

Date: February 10, 2012

From: Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS)

Title: Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code

I. Purpose

Section 2713(a)(4) of the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act), requires non-grandfathered group health plans and health insurance issuers to provide coverage for recommended women's preventive health services without cost sharing. The Affordable Care Act also added section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act (including section 2713) into ERISA and the Code to make them applicable to group health plans.

Interim final regulations were issued by the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (collectively, the Departments) on July 19, 2010 (codified at 26 CFR §54.9815-2713T; 29 CFR §2590.715-2713; and 45 CFR §147.130), which provide that a non-grandfathered group health plan or health insurance issuer must cover certain items and services, without cost sharing, as recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the Health Resources and Services Administration (HRSA). Among other things, the interim final regulations provide that, if a new recommendation or guideline is issued, a plan or issuer must provide coverage consistent with the new recommendation or guideline (with no cost sharing) for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation or guideline is issued.

HRSA was charged by statute with developing comprehensive guidelines for preventive care and screenings with respect to women, to the extent not already recommended by USPSTF. On August 1, 2011, HRSA adopted and released guidelines for women's preventive services based on recommendations developed by the Institute of Medicine at the request of HHS (Women's Preventive Services: Required Health Plan Coverage Guidelines, or HRSA Guidelines). One of HRSA's recommendations is that all Food and Drug Administration-approved contraceptives for women, as prescribed by a provider, be covered by non-grandfathered group health plans and health insurance issuers without cost sharing.

That same day, the Departments issued an amendment to the interim final regulations that provided HRSA discretion to exempt group health plans established or maintained by certain religious employers (and any group health insurance provided in connection with such plans) from any requirement to cover contraceptive services. The Departments' amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The definition of religious employer, as set forth in the amended interim final regulations, was based on existing definitions used by some States that exempt group health insurance coverage of certain religious employers from having to comply with State insurance law requirements to cover contraceptive services. This discretion to exempt the group health plans established or maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) from any requirement to cover contraceptive services was exercised by HRSA in the HRSA Guidelines, consistent with the Departments' amended interim final regulations. Therefore, this exemption now applies to any group health plan established or maintained by a qualifying religious employer (and any group health insurance coverage provided in connection with such a plan).

For all non-exempted, non-grandfathered plans and policies, the regulations require coverage of the recommended women's preventive services, including the recommended contraceptive services, without cost sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.

On January 20, 2012, Secretary Sebelius reaffirmed the exemption authorized in the amended interim final regulations. In doing so, the Secretary indicated that a temporary enforcement safe harbor would be provided to non-exempted, non-grandfathered group health plans established and maintained by non-profit organizations with religious objections to contraceptive coverage (and any health insurance coverage offered in connection with such plans). This bulletin describes the temporary enforcement safe harbor. It is available to non-exempted, non-grandfathered group health plans established or maintained by non-profit organizations whose plans have not covered contraceptive services for religious reasons at any point from the issuance date of this bulletin (i.e., February 10, 2012) onward, consistent with any applicable State law (and any group health insurance coverage provided in connection with such plans), as described herein. This temporary enforcement safe harbor provides an additional year for these group health plans and group health insurance issuers (i.e., until the first plan year beginning on or after August 1, 2013).

The Department of Labor and the Department of the Treasury agree with the need for such transitional relief and will not take any enforcement action against an employer or group health plan that complies with the conditions of the temporary enforcement safe harbor described herein.

II. Temporary Enforcement Safe Harbor

The temporary enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. Neither employers, nor group health plans, nor group health insurance issuers will be subject to any enforcement action by the Departments for failing to cover recommended contraceptive services without cost sharing in non-exempted, non-grandfathered group health plans established or maintained by an organization, including a group or association of employers within the meaning of section 3(5) of ERISA, (and any group health insurance coverage provided in connection with such plans) meeting all of the following criteria:

1. The organization is organized and operates as a non-profit entity.

2. From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan established or maintained by the organization, consistent with any applicable State law, because of the religious beliefs of the organization.

3. As detailed below, the group health plan established or maintained by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) must provide to participants the attached notice, as described below, which states that contraceptive coverage will not be provided under the plan for the first plan year beginning on or after August 1, 2012.[1]

4. The organization self-certifies that it satisfies criteria 1-3 above, and documents its self-certification in accordance with the procedures detailed herein.

III. Notice

The attached notice must be in any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of the first plan year that is on or after August 1, 2012.[2] (For example, for a calendar year plan with an open enrollment period beginning November 1, the notice must be in any application materials provided to participants on or after November 1, 2012.).

This notice is required to be provided by the group health plan (although the plan may ask another entity, such as a health insurance issuer or third-party administrator, to accept responsibility for providing the notice on its behalf). With respect to insured coverage, unless it accepts in writing the responsibility for providing the notice, a group health insurance issuer does not lose its protection under the temporary enforcement safe harbor solely because the notice is not distributed by the plan as described herein, or because the issuer relies in good faith on a representation by the plan that turns out to be incorrect.

[1] Nothing in this bulletin precludes employers or others from expressing their opposition, if any, to the final regulations or to the use of contraceptives.

[2] CMS has determined that the notice is not a collection of information under the Paperwork Reduction Act because it is "[t]he public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." 5 CFR §1320.3(c)(2).

IV. Certification

A certification must be made by the organization described in section II.[3] The certification must be signed by an organizational representative who is authorized to make the certification on behalf of the organization. The specifications for the certification are attached.

The certification must be completed and made available for examination by the first day of the plan year to which the temporary enforcement safe harbor applies.

Where to get more information:

If you have any questions regarding this bulletin, contact CCIIO at CMS at 410-786-1565 or at phig@cms.hhs.gov.

[3] CMS has determined that the certification is not a collection of information under the Paperwork Reduction Act because, although it is a third-party disclosure, it is a certification that does not entail burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. 5 CFR §1320.3(h)(1).

NOTICE TO PLAN PARTICIPANTS

The organization that sponsors your group health plan has certified that it qualifies for a temporary enforcement safe harbor with respect to the Federal requirement to cover contraceptive services without cost sharing. During this one-year period, coverage under your group health plan will not include coverage of contraceptive services.

CERTIFICATION

This form is to be used to certify that the group health plan established or maintained by the organization listed below qualifies for the temporary enforcement safe harbor, as described in HHS bulletin entitled "Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code," pertaining to coverage of FDA-approved contraceptive services for women without cost sharing.

Please fill out this form completely.

	Name of the organization sponsoring the plan
	Name of the individual who is authorized to make, and makes, this certification on behalf of the organization
	Mailing and email addresses and phone number for the individual listed above

I certify that the organization is organized and operated as a non-profit entity; and that, at any point from February 10, 2012 onward, contraceptive coverage has not been provided by the plan, consistent with any applicable State law, because of the religious beliefs of the organization.

I declare that I have made this certification, and that, to the best of my knowledge and belief, it is true and correct. I also declare that this certification is complete.

_____

Signature of the individual listed above

_____

Date

Failure to provide the requisite notice to plan participants renders a group health plan ineligible for the temporary enforcement safe harbor.